

Exhibit 89

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 - - -

4 IN RE: VALSARTAN, LOSARTAN, : MDL No. 2875
5 AND IRBESARTAN PRODUCTS : HON ROBERT B. KUGLER
6 LIABILITY LITIGATION : CIVIL NO. 19-2875 (RBK/JS)

7 _____

8 THIS DOCUMENT APPLIES TO ALL :
9 CASES :

10 - - -

11 APRIL 14, 2021

12 - - -

13 - CONFIDENTIAL INFORMATION -

14 SUBJECT TO PROTECTIVE ORDER

15 Remote Videotaped

16 Deposition, taken via Zoom, of DANIEL
17 BARRETO, commencing at 8:03 a.m., on the
18 above date, before Amanda
19 Maslynsky-Miller, Certified Realtime
20 Reporter and Notary Public in and for the
21 Commonwealth of Pennsylvania.

22 - - -

23 - - -

24 GOLKOW LITIGATION SERVICES
25 877.370.3377 ph | 917.591.5672 fax
26 deps@golkow.com

Page 2

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Page 4

1 APPEARANCES: (Continued)

2

3 ALSO PRESENT:

4

5 Kristalyn Duran, Videographer

6

7 David Marck, Teva Pharmaceuticals USA, Inc.

8

9 Rachel Gallagher, Teva Pharmaceuticals USA,

10 Inc.

11

12 - - -

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Page 3

1 APPEARANCES: (Continued)

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35 Mylan Pharmaceuticals, Inc.

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1

2 - - -

3 I N D E X

4 - - -

5 Testimony of: DANIEL BARRETO

6 By Mr. Stanoch 11

7

8 - - -

9 E X H I B I T S

10 - - -

11

12 NO. DESCRIPTION PAGE

13 Teva-133 No Bates

14 Amended Notice to Take

15 Videotaped Oral Deposition 15

16 Teva-134 TEVA-MDL2875-DEPS-000027-031

17 Consulting Agreement 22

18 Teva-135 TEVA-MDL2875-00116005-6007

19 9/16/16 E-mail, Thomas to

20 Harle 47

21 Teva-136 TEVA-MDL2875-00042539

22 Teva Corporate Standards

23 CORP-0175 71

24 Teva-137 TEVA-MDL2875-00586753

25 Teva Corporate Standard,

26 Corp-0896 85

27 Teva-138 TEVA-MDL2875-00495102-5104

28 7/6/18 E-mail, Drape to

29 Vanderweeen 124

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1	- - -	
2	E X H I B I T S	
3	- - -	
4		
5	NO. DESCRIPTION PAGE	
6	Teva-139 TEVA-MDL2875-00020376	
7	Teva CORP-0092 135	
8	Teva-140 TEVA-MDL2875-0934333-4435	
9	7/5/18 E-mail, Sawyer to Barak 153	
10	Teva-141 TEVA-MDL2875-00020519-0525	
11	7/4/18 E-mail, Barreto to Drape 167	
12	Teva-142 TEVA-MDL2875-00064409-4412	
13	7/12/18 E-mail, Barreto to Truemper 174	
14	Teva-143 TEVA-MDL2875-00020744	
15	7/5/18 E-mail, Barreto to Koller-Dette 180	
16	Teva-144 TEVA-MDL2875-00057196-7197	
17	7/6/18 E-mail, Sawyer to Drape 205	
18	Teva-145 TEVA-MDL2875-00021073-1074	
19	7/13/15 E-mail, Var to Koller-Dette 218	
20	Teva-146 TEVA-MDL2875-00020898-0903,	
21	7/11/18 E-mail, Barreto to Lyons 226	
22	Teva-147 TEVA-MDL2875-00020853-0854	
23	7/8/18 E-mail, Barreto to Drape 237	
24	Teva-148 TEVA-MDL2875-00549865-9886	
	7/9/18 E-mail, Osmian to Baeder 248	

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2	E X H I B I T S	
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4		
5	NO. DESCRIPTION PAGE	
6	Teva-149 TEVA-MDL2875-00042637-2649	
7	8/14/18 Valsartan Testing Strategy 277	
8	Teva-150 TEVA-MDL2875-00067084-7087	
9	12/13/18 E-mail, Drape to Barreto 294	
10	Teva-151 TEVA-MDL2875-00731926	
11	NDA/ANDA Field Alert 297	
12	Teva-152 TEVA-MDL2875-00073603-3612	
13	11/16/18 E-mail, Redmond to Barreto 301	
14	Teva-153 TEVA-MDL2875-00415117	
15	Site Risk Assessment Protocol 328	
16	Teva-154 TEVA-MDL2875-00132980	
17	10/2/17 E-mail, McClain to Barreto 350	
18	Teva-155 TEVA-MDL2875-00546489-6492	
19	2/15/19 E-mail, Lyons to Gray 363	
20	Teva-156 TEVA-MDL2875-00083812-3877	
21	6/15/16 E-mail, Myers to Cheasty 376	
22	Teva-157 TEVA-MDL2875-00495893-5896	
23	3/27/19 E-mail, Vanderween to Barreto 381	
24	Teva-158 TEVA-MDL2875-00246006	
	2/1/17 E-mail, Reitman to Hatt 383	

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1	- - -	
2	E X H I B I T S	
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4		
5	NO. DESCRIPTION PAGE	
6	Teva-159 TEVA-MDL2875-00246006	
7	2/1/17 E-mail, Reitman to Hatt 384	
8	Teva-160 TEVA-MDL2875-00400799-0905	
9	6/13/19 E-mail, Hoover to Hatt 397	
10	Teva-161 TEVA-MDL2875-00067532-7537	
11	1/1/19 E-mail, Weissbazak to Denac 408	
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1	- - -	
2	DEPOSITION SUPPORT INDEX	
3	- - -	
4		
5	Direction to Witness Not to Answer	
6	Page Line Page Line Page Line	
7	413 11	
8		
9		
10	Request for Production of Documents	
11	Page Line Page Line Page Line	
12	None	
13		
14		
15	Stipulations	
16	Page Line Page Line Page Line	
17	10 1	
18		
19		
20	Question Marked	
21	Page Line Page Line Page Line	
22	None	
23		
24		

<p>Page 10</p> <p>1 - - -</p> <p>2 (It is hereby stipulated and</p> <p>3 agreed by and among counsel that</p> <p>4 sealing, filing and certification</p> <p>5 are waived; and that all</p> <p>6 objections, except as to the form</p> <p>7 of the question, will be reserved</p> <p>8 until the time of trial.)</p> <p>9 - - -</p> <p>10 VIDEO TECHNICIAN: We are</p> <p>11 now on the record. My name is</p> <p>12 Kristalyn Duran, a videographer</p> <p>13 for Golkow Litigation Services.</p> <p>14 Today's date is April 14, 2021,</p> <p>15 and the time is 8:03 a.m.</p> <p>16 This deposition is being</p> <p>17 held by remote Zoom in the matter</p> <p>18 of Valsartan, Losartan, and</p> <p>19 Irbesartan Products Liability</p> <p>20 Litigation. The deponent today is</p> <p>21 Daniel Barreto.</p> <p>22 All parties to this</p> <p>23 deposition are appearing remotely</p> <p>24 and have agreed to the witness</p> <p>Page 11</p> <p>1 being sworn in remotely. All</p> <p>2 appearances are noted on the</p> <p>3 stenographic record.</p> <p>4 Will the court reporter</p> <p>5 please administer the oath?</p> <p>6 - - -</p> <p>7 DANIEL BARRETO, after having</p> <p>8 been duly sworn, was examined and</p> <p>9 testified as follows:</p> <p>10 - - -</p> <p>11 EXAMINATION</p> <p>12 - - -</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Good morning, Mr. Barreto.</p> <p>15 A. Good morning. How are you?</p> <p>16 Q. Good. Thank you.</p> <p>17 My name is David Stanoch,</p> <p>18 I'm an attorney for the plaintiffs in</p> <p>19 this action. I'll be asking you most of</p> <p>20 the questions today.</p> <p>21 Sir, have you been deposed</p> <p>22 before?</p> <p>23 A. No.</p> <p>24 Q. I'll go over some of the</p>	<p>Page 12</p> <p>1 ground rules, then, for today.</p> <p>2 Obviously, you know,</p> <p>3 probably, that I'll be asking you a</p> <p>4 series of questions, and you'll be</p> <p>5 providing answers. Everything we and</p> <p>6 anyone else says will be taken down by</p> <p>7 the stenographer and on the video.</p> <p>8 Because of that, I just ask</p> <p>9 that you make sure to pause before you</p> <p>10 answer a question so we don't speak over</p> <p>11 each other, and I'll afford you the same</p> <p>12 courtesy.</p> <p>13 Is that okay?</p> <p>14 A. That would be perfect.</p> <p>15 Thank you.</p> <p>16 Q. If you do not understand a</p> <p>17 question, please tell me and I'll attempt</p> <p>18 to rephrase. Otherwise, I'm going to</p> <p>19 assume that you understand.</p> <p>20 Is that fair?</p> <p>21 A. It is. Thank you.</p> <p>22 Q. From time to time, your</p> <p>23 attorney may object. Unless she</p> <p>24 instructs you otherwise, you should</p> <p>Page 13</p> <p>1 answer the question.</p> <p>2 Do you understand that?</p> <p>3 A. I do.</p> <p>4 Q. And from time to time, you</p> <p>5 or someone else may need a break, just</p> <p>6 simply say so, if you need a refreshment</p> <p>7 break or to stretch your legs. I'd just</p> <p>8 ask that if a question is pending, you</p> <p>9 answer the question and then we can take</p> <p>10 the break.</p> <p>11 Is that okay?</p> <p>12 A. That will be perfect.</p> <p>13 Q. Great. And, for the record,</p> <p>14 where are you located for today's remote</p> <p>15 video deposition?</p> <p>16 A. I'm in Oklahoma City.</p> <p>17 Q. Is that where you currently</p> <p>18 reside, sir?</p> <p>19 A. Yes, it is.</p> <p>20 Q. And you're in your home</p> <p>21 right now?</p> <p>22 A. I am located at the law</p> <p>23 office -- firm here in Oklahoma City.</p> <p>24 Q. Your counsel's office in</p>
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1 Oklahoma City?

2 A. Yes.

3 Q. Is anybody else in the room

4 with you?

5 A. Yes.

6 Q. Who is in the room with you?

7 A. Victoria Lockard.

8 Q. So Ms. Lockard traveled to

9 Oklahoma City. That was very nice of

10 her.

11 Anybody else in the room?

12 A. No, sir.

13 Q. Okay. Great.

14 You understand you are

15 testifying today as a corporate designee

16 on behalf of Teva on certain topics,

17 correct?

18 A. I do understand that, yes.

19 Q. I'm going to attempt to mark

20 an exhibit, if you bear with me, sir.

21 MR. STANOCH: This, for the

22 record, will be, I believe, Teva

23 133.

24 MS. LOCKARD: I'm not seeing

Page 15

1 the link on the chat for the

2 exhibits. Is that supposed to be

3 up already?

4 - - -

5 (Whereupon, Exhibit

6 Teva-133, No Bates, Amended Notice

7 to Take Videotaped Oral

8 Deposition, was marked for

9 identification.)

10 - - -

11 MR. STANOCH: Mr. Barreto,

12 and I guess, Ms. Lockard, do you

13 now have access and can see Teva

14 133?

15 THE WITNESS: Where would I

16 see that? Is that on the chat?

17 MS. LOCKARD: Give us one

18 moment.

19 MR. STANOCH: Do you want us

20 to go off the record, Ms. Lockard?

21 MS. LOCKARD: Sure. That's

22 fine.

23 MR. STANOCH: Let's go off

24 the record for a moment, please.

Page 16

1 VIDEO TECHNICIAN: The time

2 is 8:08 a.m. Off the record.

3 - - -

4 (Whereupon, a brief recess

5 was taken.)

6 - - -

7 VIDEO TECHNICIAN: The time

8 is now 8:09 a.m. Back on the

9 record.

10 BY MR. STANOCH:

11 Q. Mr. Barreto, welcome back.

12 Thanks for bearing with the technical

13 issues.

14 I understand now you're able

15 to view the marked exhibits; is that

16 right?

17 A. That is correct.

18 Q. Great. So as I was saying

19 before, Teva-133 is the amended notice to

20 take the videotaped oral deposition of

21 you.

22 Do you see that?

23 A. Yes, I do.

24 Q. Have you seen this before?

Page 17

1 A. Yes, I have.

2 Q. And if you flip to the

3 exhibit -- to Exhibit A, there are a

4 number of topics listed.

5 Do you see that?

6 A. Yes, I have.

7 Q. My understanding is that

8 you're designated as the corporate

9 designee on behalf of Teva on all the

10 topics listed except, and your counsel

11 can correct me, 49 and 56; is that

12 correct?

13 MS. LOCKARD: I believe

14 that's correct.

15 Yep, that's correct.

16 BY MR. STANOCH:

17 Q. Is that your understanding

18 as well, Mr. Barreto?

19 A. It is. Correct.

20 Q. Great. Thank you.

21 And just for the record,

22 I'll note the topics, then, less 49 and

23 56, on which Mr. Barreto is designated is

24 Topics 1, 2, 3, 4, 17, 18, 19, 29, 30,

<p style="text-align: right;">Page 18</p> <p>1 31, 44, 45, 46, 47, 48 and 50.</p> <p>2 MS. LOCKARD: Correct. And</p> <p>3 let me just add, too, you know, as</p> <p>4 counsel knows, but for the record,</p> <p>5 we also designated Tony Binsol on</p> <p>6 some of these topics as well.</p> <p>7 And so, you know, as we</p> <p>8 discussed in our meet-and-confers,</p> <p>9 there may be some more specifics</p> <p>10 of things like, you know, testing</p> <p>11 and analysis that will be reserved</p> <p>12 for Tony.</p> <p>13 But if Mr. Barreto is not</p> <p>14 able to answer them, then, you</p> <p>15 know, we'll make sure that Mr.</p> <p>16 Binsol is able to answer.</p> <p>17 MR. STANOCH: Acknowledged.</p> <p>18 Thank you, counsel.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Mr. Barreto, what did you do</p> <p>21 to prepare for today's deposition?</p> <p>22 And, again, I don't want to</p> <p>23 hear anything about what you said to your</p> <p>24 counsel or not. So I'm asking sort of</p>	<p style="text-align: right;">Page 20</p> <p>1 counsel on behalf of Teva to prepare for</p> <p>2 this deposition, whether it was in person</p> <p>3 or by phone? Just the number of</p> <p>4 meetings.</p> <p>5 A. Sure. I want to say several</p> <p>6 times. I want to say between four and</p> <p>7 six times that we have met both in person</p> <p>8 and via telephone.</p> <p>9 Q. And each time was that with</p> <p>10 one or more in-house or outside counsel</p> <p>11 for Teva?</p> <p>12 A. That is correct.</p> <p>13 Q. Were there ever any</p> <p>14 non-attorneys in any of the prep meetings</p> <p>15 that you had for today's deposition?</p> <p>16 A. No.</p> <p>17 Q. Approximately how much time</p> <p>18 do you think you spent in meetings,</p> <p>19 telephone or in person, with counsel to</p> <p>20 prepare for today's deposition?</p> <p>21 A. I would say about 15 hours.</p> <p>22 We met a couple of times in person here</p> <p>23 in Oklahoma City and via phone a couple</p> <p>24 of hours. So I want to say between 15,</p>
<p style="text-align: right;">Page 19</p> <p>1 what you looked at and things like that.</p> <p>2 A. I received a number of</p> <p>3 documents that pertained to the</p> <p>4 discussion that we were going to have</p> <p>5 today. And I have gone over those</p> <p>6 documents to make sure that I'm fully</p> <p>7 prepared and refreshed, in terms of, you</p> <p>8 know, the understanding that I have about</p> <p>9 the discussions that we will have with</p> <p>10 respect to this document that you just --</p> <p>11 Teva-133, that you just shared with me.</p> <p>12 Q. Great. When were you first</p> <p>13 contacted by Teva, or someone on Teva's</p> <p>14 behalf, that you may be a potential</p> <p>15 witness in this litigation?</p> <p>16 A. Yeah, that was, I would say,</p> <p>17 sometime around January of this year.</p> <p>18 Q. Was that one of Teva's</p> <p>19 counsel in this litigation who contacted</p> <p>20 you?</p> <p>21 A. Yes. That was Rachel</p> <p>22 Gallagher.</p> <p>23 Q. And approximately how many</p> <p>24 times did you have a meeting with any</p>	<p style="text-align: right;">Page 21</p> <p>1 20 hours.</p> <p>2 Q. Approximately how many</p> <p>3 documents do you think you reviewed to</p> <p>4 prepare for today's deposition, sir?</p> <p>5 A. I want to say that I've</p> <p>6 looked at at least 50 to 100 documents,</p> <p>7 you know.</p> <p>8 Q. About how much time did you</p> <p>9 spend on your own preparing for today's</p> <p>10 deposition, whether reviewing documents</p> <p>11 or otherwise, outside of the meetings</p> <p>12 with any counsel?</p> <p>13 A. I spent about, I want to</p> <p>14 say, 30 to maybe 50 hours going over, you</p> <p>15 know, the documents that were given to</p> <p>16 me.</p> <p>17 Q. And I understand, sir, that</p> <p>18 you had been, but at some point -- but</p> <p>19 are no longer employed by Teva, right?</p> <p>20 A. That is correct.</p> <p>21 Q. And you have a consulting</p> <p>22 agreement with Teva as it relates to your</p> <p>23 testimony in this litigation; is that</p> <p>24 right?</p>

Page 22

1 A. I do.
2 MR. STANOCH: I'm going to
3 mark what I believe that agreement
4 is as Teva-134.
5 - - -
6 (Whereupon, Exhibit
7 Teva-134,
8 TEVA-MDL2875-DEPS-000027-031,
9 Consulting Agreement, was marked
10 for identification.)
11 - - -
12 BY MR. STANOCH:
13 Q. Are you able to see that,
14 sir?
15 A. I'm opening it.
16 Yes.
17 Q. Is this the consulting
18 agreement that you have with Teva in this
19 litigation?
20 A. It is.
21 Q. And it's an agreement from
22 Ms. Lockard, Teva's outside counsel in
23 this case, and it's dated February 19th,
24 2021?

Page 23

1 A. That is correct.
2 Q. And it looks like you signed
3 the agreement at the end; that's your
4 signature, right, on Page 5?
5 A. I'm looking at it.
6 Yes, I did.
7 Q. And it was signed February
8 24th, 2021, yes?
9 A. That is correct.
10 Q. And you can refer to this
11 exhibit if you want.
12 My question is, I understand
13 you're being compensated for your time,
14 for your testimony or otherwise, in this
15 case; is that right?
16 A. I'm not being compensated
17 for the testimony. I'm being compensated
18 for the time lost from doing my regular
19 business.
20 Q. Fair enough.
21 And in Paragraph 5, I
22 believe, is the compensation for your
23 time spent in connection with this
24 matter; is that right?

Page 24

1 A. That is correct, yes. And
2 that includes -- I'm sorry.
3 Q. No, please, please. Go
4 ahead.
5 A. -- the time that I spent
6 reviewing documentation.
7 Q. Understood. That's part of
8 where I was going to go.
9 It looks like you're being
10 reimbursed at a rate of \$286.68 per hour;
11 is that right?
12 A. That is correct.
13 Q. And you're being compensated
14 at that rate both for your preparation
15 for this deposition as well as your time
16 for this deposition; is that fair?
17 A. The time, yeah -- yes,
18 correct.
19 Q. Have you been paid yet by
20 Teva, under this consulting agreement,
21 for any of your time?
22 A. No, sir.
23 Q. I just want to touch briefly
24 on your educational and professional

Page 25

1 background, sir.
2 I understand that you
3 graduated from the University of Puerto
4 Rico with a Bachelor's Degree in biology;
5 is that right?
6 A. That is correct.
7 Q. What year did you graduate,
8 sir?
9 A. That was in 1970 -- if I
10 recall, 1978.
11 Q. And did you ever obtain any
12 other educational degree after that
13 Bachelor's Degree in biology from the
14 University of Puerto Rico in 1978?
15 A. No.
16 Q. And then you're in the
17 workforce.
18 You went right to -- I'm
19 sorry, you went right to work after you
20 obtained your degree, correct?
21 A. Pretty much immediately,
22 yes. While I was at the university, I
23 was actually already working for the U.S.
24 Food and Drug Administration under a

Page 26

1 special program for college students.
2 Q. Got it.
3 And it looks like you held
4 roles at the U.S. Food and Drug
5 Administration through about November of
6 1996?
7 A. Yes.
8 Q. And we'll call the -- we'll
9 call the U.S. Food and Drug
10 Administration "FDA" today; is that okay?
11 A. That's fine.
12 Q. And then it looks like you
13 went into the private sector in November
14 of '96?
15 A. That is correct.
16 Q. And you held a number of --
17 you held a number of different jobs at
18 different companies.
19 Eventually you were at
20 Sanofi-Aventis beginning in January 2012,
21 right?
22 A. Correct.
23 Q. I'm sorry, prior to that,
24 you were at CR Bard from April to

Page 27

1 December of 2011, right?
2 A. That is correct.
3 Q. So that was about, what,
4 about eight months you were at CR Bard?
5 A. Oh, no, that would not be
6 correct. Sorry.
7 Q. I mean, I can put your C.V.
8 up. I'm just trying to walk through it.
9 A. Unless there is some kind of
10 a dating mistake. But I spent more time
11 at CR Bard.
12 I was at CR Bard from August
13 2008 through December 2011.
14 Q. Oh, I see. You had one
15 position, and then you went into another
16 position. I see.
17 A. Yes, sir.
18 Q. Got it.
19 And then you went to Sanofi
20 January 2012?
21 A. Correct.
22 Q. And then you were there in
23 two positions through the end of 2016?
24 A. Yes, sir.

Page 28

1 Q. And then in December 2016
2 you went to Lachman, L-A-C-H-M-A-N,
3 Consultants?
4 A. That is correct.
5 Q. And what was Lachman
6 Consultants?
7 A. So Lachman Consultants is a
8 company that is dedicated to providing
9 consulting and supporting -- technical
10 support services to pharmaceutical -- in
11 the pharmaceutical industry. But that
12 also includes medical device companies,
13 regulatory issues as well.
14 Q. And then it looks like you
15 were there for about six or seven months,
16 and then you're listed here as going to
17 DBC Consulting, July 2017 to September
18 2017?
19 A. That is correct. DBC was
20 just the first name that I gave to my
21 first consulting, small operation.
22 Q. I see. So you sort of went
23 into business yourself for a couple of
24 months; is that fair?

Page 29

1 A. That is correct.
2 Q. And then you started, it
3 looks like, at Teva in September of 2017?
4 A. That is correct.
5 Q. Briefly, what was the reason
6 for the transition from Lachman to your
7 own business for a couple of months to
8 Teva?
9 A. It's -- after I left
10 Lachman, I had decided that, you know, I
11 was going to try to do some consulting
12 work to see how that would just work for
13 me.
14 And it just started to work
15 very well. But then, of course, later on
16 an opportunity for work at Teva came.
17 Q. Did you have an offer from
18 Teva when you parted from Lachman
19 Consultants?
20 A. No. That was a few months
21 later.
22 Q. And what were the
23 circumstances of your departure from
24 Lachman Consultants?

<p>Page 30</p> <p>1 A. It was, basically, the 2 arrangement that we had, at least for 3 myself, in terms of the working 4 conditions there, the demands of the job, 5 it was not something that I found to be 6 what I wanted to do. 7 So I decided that the best 8 way to pursue something that I liked to 9 do was just to leave the organization. 10 Q. Got it. And then after 11 starting your own consulting business for 12 a couple of months, you began a position 13 at Teva in September 2017? 14 A. That is correct. 15 Q. And then you were there, it 16 looks like, through March 2020? 17 A. Physically I was there until 18 January 2020. And then the contract 19 basically expired in March 2020. 20 Q. I see. And then after that, 21 it looks like you went back into running 22 your own consulting business; is that 23 fair? 24 A. That is correct.</p> <p>Page 31</p> <p>1 Q. And that's PharmQ, 2 F-H-A-R-M-Q, Global Consulting? 3 A. That is correct. 4 Q. And you're the president and 5 CEO of that consulting firm? 6 A. That is correct. 7 Q. And that's been your role 8 since approximately April of 2020? 9 A. Correct. 10 Q. And what were the 11 circumstances about your departure from 12 Teva? 13 A. There was an organizational 14 change and reorganization in terms of, 15 you know, priorities for the company. So 16 as part of that reorganization, the 17 company decided that I would no -- not be 18 part of that reorganization. 19 So there was an 20 understanding that that would be the 21 case, and so I left. 22 Q. Got it. And did you 23 continue to receive any compensation of 24 any kind from Teva after your departure?</p>	<p>Page 32</p> <p>1 A. We engaged in a separation 2 agreement. And that separation agreement 3 dictated, you know, a certain amount of 4 compensation that I would be granted. 5 Q. And how long was the 6 compensation to run from that separation 7 agreement? 8 A. So in this case, it was 9 intended to be a one-year understanding. 10 Q. Okay. So, approximately, 11 the compensation you were receiving under 12 your separation agreement from Teva ran 13 from a year from sometime in March of 14 2020? 15 A. That is correct. 16 Q. So that year, it sounds like 17 it just came up, right? 18 A. That's correct. 19 Q. Okay. So as of right now, 20 today, you're not receiving any 21 compensation from Teva under that 22 separation agreement; is that right? 23 A. I am not. 24 Q. I want to focus on your time</p> <p>Page 33</p> <p>1 at Teva. 2 Your position was senior 3 global VP quality and compliance; is that 4 right? 5 A. That is correct. 6 Q. And that was your position 7 you held the entire two or three years 8 that you were at Teva; is that right? 9 A. That is correct. 10 Q. And where were you 11 physically located when you worked at 12 Teva? 13 A. So I was residing in New 14 Jersey, in a city called New Providence. 15 And my offices were located in 16 Parsippany. 17 Q. Got it. And if you could 18 just tell me generally what your roles 19 and responsibilities were at Teva as 20 senior global VP quality and compliance? 21 A. Certainly. I had 22 responsibilities for the overall -- to 23 start with, we had the quality systems 24 management program. So we had everything</p>
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<p style="text-align: right;">Page 34</p> <p>1 that had to do with the corporate 2 standards and policies and procedures. 3 So I had a group of people who were 4 performing this type of work. 5 We had responsibilities for 6 the global audit program that fell under 7 my responsibility. So we had a number of 8 people who -- auditors who would go to 9 the sites and to suppliers to perform 10 audits in accordance with Teva's 11 expectations. 12 I had a group of people who 13 were doing what we called regulatory 14 intelligence, which is more around 15 getting information that would help us to 16 be up to date with the regulatory 17 standards coming from the agencies. 18 I was the lead person for 19 what's called the MAC process, which is 20 the market action committee. So whenever 21 we had a product that needed to be 22 assessed, whether that product should be 23 recalled or not, that was a 24 responsibility.</p>	<p style="text-align: right;">Page 36</p> <p>1 after your joining Teva? 2 A. That would have been before. 3 So my knowledge of those details is very 4 limited. It's more, you know, general 5 knowledge and understanding. 6 Q. For sure. 7 And I'm not going to quiz or 8 ask you about the specifics of that, sir. 9 I just -- as we go forward today, I may 10 refer to Teva. And if we can be on the 11 same page when I say "Teva," I'm going to 12 mean, you know, Teva, the global 13 organization as it existed when you were 14 there from September 2017 forward; is 15 that fair? 16 A. It is fair. Thank you. 17 Q. So that may encompass, for 18 instance, legacy Actavis or legacy 19 Allergan generic operations which had 20 been absorbed by Teva by the time you got 21 there; is that fair? 22 A. That's fair. And I'm quite 23 familiar with those operations. 24 Q. Very good, sir.</p>
<p style="text-align: right;">Page 35</p> <p>1 I had, also, 2 responsibilities for supporting 3 troubleshooting issues within the 4 organization, across the globe, providing 5 organizational support, inspection 6 readiness for the organization as well. 7 Q. Thank you for that. 8 And you touched on this, and 9 it may be evident from the title itself, 10 but your responsibilities were global in 11 nature; is that right? 12 A. That is correct. 13 Q. So your responsibilities 14 would touch on the different things you 15 listed off before for Teva's operations 16 worldwide, not just for the United 17 States; is that fair? 18 A. That is correct. 19 Q. And just your own 20 understanding -- Teva obviously has 21 acquired a number of entities over time. 22 Do you recall, yourself, 23 when, I guess, the Allergan acquisition 24 by Teva occurred? Was that before or</p>	<p style="text-align: right;">Page 37</p> <p>1 If I want to focus on those 2 operations specifically as apart from 3 sort of the global Teva entity, I'll try 4 to focus us, to say something like, the 5 legacy Actavis facility in Malta or 6 something like that; is that okay, 7 generally? 8 A. It is okay. I understand. 9 Q. And, obviously, when we get 10 to those areas, please feel free, if you 11 need to clarify something about the 12 facility, just say so, just so we're on 13 the same page. 14 A. Yes, sir. 15 Q. Okay. And, you know, while 16 we're at it, just some more housekeeping 17 for terminology. 18 Throughout the day we'll 19 probably reference the phrase or term 20 "API." 21 Can we agree that's active 22 pharmaceutical ingredient? 23 A. Yes. 24 Q. And that's the same thing as</p>

<p style="text-align: right;">Page 38</p> <p>1 a -- I believe it's called a drug 2 substance? 3 A. It is correct. 4 Q. And can you just give me a 5 general understanding, so we're on the 6 same page, of what an API or a drug 7 substance is? 8 A. So an API or a drug 9 substance is the chemical active 10 ingredient that is produced and that 11 serves as the basis for the ingredient 12 that provides the therapeutic value to 13 the patient. 14 Q. Great. Thank you. And 15 throughout the day we may refer to drug 16 product or finished dose. 17 My understanding is that's 18 sort of the tablet or other medication 19 that a patient might ingest; is that 20 right? 21 A. That is correct. 22 Q. So the API is the chemical 23 active ingredient that goes into the 24 finished-dose product, right?</p>	<p style="text-align: right;">Page 40</p> <p>1 terminology, a couple other things. 2 You're familiar with the 3 phrase "NDA" as well as "ANDA," yes? 4 A. Yes, I am. 5 Q. NDA is new drug application? 6 A. That is correct. 7 Q. A-N-D-A, or ANDA, is 8 abbreviated new drug application? 9 A. That is correct. 10 Q. And, again, just very high 11 level, so we're on the same page, can you 12 just tell us what an NDA and an ANDA are? 13 A. So an NDA is a submission 14 that is made by an innovator drug 15 manufacturer. So it's around new drugs 16 that are developed for which certain 17 expectations are set. 18 The ANDA attempts to -- will 19 be considered to be a clone or a 20 simulation or, let's say, a generic 21 example of what the innovator product is. 22 Q. And in this litigation, the 23 valsartan drugs we're talking about, Teva 24 sold, in the United States, generic</p>
<p style="text-align: right;">Page 39</p> <p>1 A. That is correct. 2 Q. Great. You're familiar with 3 the term "GMP," right? 4 A. Yes, I am. 5 Q. That's good manufacturing 6 practices? 7 A. That is correct. 8 Q. Sometimes it's called CGMP, 9 current good manufacturing practices? 10 A. That is correct. 11 Q. And we'll get into it in 12 more detail when we get to documents, 13 sir. 14 But just at a very high 15 level, could you tell us all your 16 understanding of what GMP -- GMPs are? 17 A. The GMPs are the regulations 18 that were developed by the -- in this 19 case, the U.S. Food and Drug 20 Administration in response to the 21 expectations set by the Food and Drug 22 Act. They are under what's called 21 CFR 23 Part 2. 24 Q. And while we're at the</p>	<p style="text-align: right;">Page 41</p> <p>1 valsartan, correct? 2 A. That is correct. 3 Q. And so that would have been 4 subject to one or more ANDAs that Teva or 5 a predecessor entity had submitted to the 6 FDA, right? 7 A. That is -- that is correct. 8 Q. And as an ANDA holder, Teva 9 would have certain obligations under the 10 regulations and the FDCA, correct? 11 A. Correct. 12 Q. One of those obligations 13 would be to ensure the safety and 14 effectiveness of the drug's proposed use; 15 is that fair? 16 A. I would say that the 17 responsibilities include safety, 18 efficacy, quality and purity for the 19 drugs that are marketed in the United 20 States. 21 Q. Fair enough. 22 And would those obligations 23 extend also to the appropriateness of the 24 labeling of the product?</p>

<p>Page 42</p> <p>1 A. Correct.</p> <p>2 Q. Again, I want to talk a</p> <p>3 little bit about the integration of</p> <p>4 certain legacy Actavis or Allergan</p> <p>5 operations. And, again, this isn't a</p> <p>6 corporate relationship test, sir, it's</p> <p>7 really just specifically with your</p> <p>8 duties.</p> <p>9 You mentioned that part of</p> <p>10 your duties were to understand or oversee</p> <p>11 Teva's standard operating procedures; is</p> <p>12 that right?</p> <p>13 A. That is correct.</p> <p>14 Q. So did legacy Allergan or</p> <p>15 Actavis facilities have their own SOPs at</p> <p>16 the time that they were integrated into</p> <p>17 Teva?</p> <p>18 A. At the time they were</p> <p>19 integrated, I'm sure they had their own</p> <p>20 policies and procedures, yes.</p> <p>21 Q. Were you involved in any way</p> <p>22 in any timetable for the integration of</p> <p>23 those legacy facilities becoming part of</p> <p>24 and having to adopt Teva's own SOPs?</p> <p>Page 43</p> <p>1 A. As part of my job when I</p> <p>2 joined the company in 2017, every time</p> <p>3 that a corporate policy or procedure was</p> <p>4 developed, implemented or revised, that</p> <p>5 procedure would go to every single one of</p> <p>6 the facilities within the Teva network,</p> <p>7 regardless of whether they were Actavis,</p> <p>8 former legacy Actavis or whatever.</p> <p>9 Q. That would be for, I guess,</p> <p>10 new procedures; is that right?</p> <p>11 A. That would be for all</p> <p>12 procedures.</p> <p>13 Q. Okay. So -- so what I'm</p> <p>14 trying to understand is, let's say --</p> <p>15 again, I'll just use the -- let me back</p> <p>16 up.</p> <p>17 You understand there was a</p> <p>18 legacy Actavis facility in Malta that</p> <p>19 purchased valsartan API and made</p> <p>20 valsartan finished dose for sale into the</p> <p>21 U.S. market, yes?</p> <p>22 A. Yes.</p> <p>23 Q. And I think that was -- what</p> <p>24 do you want to call that? The Malta</p>	<p>Page 44</p> <p>1 facility; is that okay?</p> <p>2 A. That will be fine.</p> <p>3 Q. Okay. So at the time the</p> <p>4 Malta facility was then part of Teva, it</p> <p>5 might have had an SOP for, what,</p> <p>6 packaging, itself, right?</p> <p>7 A. Uh-huh.</p> <p>8 Q. Yes?</p> <p>9 A. Yes.</p> <p>10 Q. And Teva may have had its</p> <p>11 own SOP for packaging, right?</p> <p>12 A. That is possible.</p> <p>13 Q. Sure. And I'm just asking,</p> <p>14 were you aware of a process by which that</p> <p>15 legacy Actavis SOP would be formally</p> <p>16 superceded by the Teva one so there</p> <p>17 wasn't two contradictory policies about</p> <p>18 the same thing?</p> <p>19 A. Understood. I'm sure that</p> <p>20 there was a transition that took place.</p> <p>21 I don't know exactly the speed of that</p> <p>22 transition at the time when legacy</p> <p>23 product was acquired.</p> <p>24 But I'm sure that one of the</p> <p>Page 45</p> <p>1 things that the audit program from the</p> <p>2 company would do would be to ensure two</p> <p>3 things. One, that there is a procedure</p> <p>4 that sets the expectations. And, two, if</p> <p>5 that procedure was not according to Teva</p> <p>6 expectations, that that communication</p> <p>7 would take place. And then -- and then</p> <p>8 adjustments, revisions to that procedure</p> <p>9 would be made.</p> <p>10 For the most part, I would</p> <p>11 probably expect that the differences</p> <p>12 between the procedure and expectations</p> <p>13 set by Teva and what the companies had at</p> <p>14 the time were probably about the same,</p> <p>15 if -- if I could be fair with that</p> <p>16 statement.</p> <p>17 Q. That's fine. And throughout</p> <p>18 the day, if we talk about standard</p> <p>19 operating procedures, I just want to have</p> <p>20 the table set so that if I put one</p> <p>21 from -- that says a Teva policy from</p> <p>22 2018, we're all going to believe that it</p> <p>23 would be applicable to all the facilities</p> <p>24 as they stood unless -- even if, say, the</p>
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1 Malta facility had something that had
2 been superceded.
3 That's what I'm trying to
4 get at, you understand, so you have an
5 idea?
6 A. I understand.
7 Q. Okay. And if you have any
8 reason to think that's not the case any
9 time I put a policy in front of you, feel
10 free to speak up, okay?
11 A. Will do. Okay.
12 Q. Great.
13 I'll put it in front of you
14 in a moment, but do you have a general
15 understanding that Teva had a policy
16 concerning contract manufacture and
17 analysis?
18 A. Yes.
19 Q. And that would be with
20 regards to outsourced activities for
21 manufacturing or analysis of substances
22 or products, right?
23 A. Have you uploaded that
24 document already?

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1 Q. I'll put it in front of you
2 right now, sir.
3 A. Okay.
4 MR. STANOCH: I'm putting in
5 front of you Teva Exhibit-135.
6 For the record, I'll state it's
7 Bates ending 00116005.
8 - - -
9 (Whereupon, Exhibit
10 Teva-135,
11 TEVA-MDL2875-00116005-6007,
12 9/16/16 E-mail, Thomas to Harle,
13 was marked for identification.)
14 - - -
15 BY MR. STANOCH:
16 Q. Tell me when you see it,
17 sir.
18 A. Let me refresh this. Yes,
19 135.
20 Did you say you were sharing
21 a standard, or is this an e-mail?
22 Q. Well, it's an e-mail from a
23 Michael Thomas to various folks attaching
24 a corporate standard, Corp-0046.

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1 Let me back up.
2 Do you see --
3 A. I see it now.
4 Q. -- the first page of the
5 exhibit?
6 A. I see it now.
7 Q. And you see the first page
8 is an e-mail from Mr. Michael Thomas to
9 others.
10 Do you see that?
11 A. I see that.
12 Q. And it says in the body,
13 among other things, The attached
14 corporate standards are now effective.
15 And then it lists Corp-0046?
16 A. Yep.
17 Q. Great. And then if you --
18 A. Yes.
19 Q. Great.
20 And if you just flip a
21 couple of pages, you'll get to the actual
22 policy that was the attachment to the
23 e-mail.
24 A. I am there.

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

Page 52

[REDACTED]

18 Q. What is a change control?
19 A. So a change control is
20 whenever a specific activity is going to
21 be revised to be performed in a different
22 way. It could also include a change of
23 specification.
24 So anything -- anything that

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[REDACTED]

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1 is a change to what is already known or
2 established, then it has to be managed
3 through the change control process.
4 Q. So an API supplier to Teva
5 wishing to change its manufacturing
6 process for the API would be subject to
7 this change control procedure, right?
8 A. That is correct.
9 Q. And an API supplier of
10 Teva's wishing to change the testing
11 specifications for the API it's supplying
12 to Teva would be subject to this change
13 control procedure, correct?
14 A. That is correct.
15 Q. And an API manufacturer
16 supplying API to Teva who wishes to
17 change the subcontractors it intends to
18 use, it would have to first under -- get
19 authorization from Teva, and then if
20 there was a change involved, utilize the
21 change control procedure; is that right?
22 A. If the conditions under
23 which the -- that understanding exist,
24 yeah, it would indicate so.

Page 54

[REDACTED]

Page 56

[REDACTED]

6 Q. What does it mean for a
7 contractor to be approved?
8 A. So the approval -- first, I
9 think it's important to make a
10 distinction that I think is important at
11 this point.
12 When we talk about contract
13 manufacturing, I think it's a concept
14 that is also one that has to be more
15 defined. Because when we engage in
16 contract manufacturing in this
17 environment, that means that we are
18 asking a company to make a product on our
19 behalf, for us. It's usually our
20 product. The same applies to
21 laboratory -- contract laboratory
22 testing.
23 So I think it's important to
24 make that distinction, number one.

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1 A. Can we -- can you take me
2 back to the section that you're talking
3 about?
4 Q. Sure, sure, sure.
5 Let's go to Section 5.1.2,
6 sir. Tell me when you're there.
7 A. Can you ask the question,
8 please?
9 Q. Sure.
[REDACTED]

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1 Number two, approved means
2 that that facility has been -- has been
3 audited, that facility has been assessed
4 in terms of their capabilities to do the
5 work that we would expect them to do
6 under the CGMP conditions and the Teva
7 expectations from, you know, our
8 standards.
[REDACTED]

16 But I think it's important
17 to clarify that I see that for a contract
18 manufacturing activity, which is within
19 that strict definition, that quality
20 agreement is definitely one that you have
21 to have, because that contract
22 manufacturing facility is operating under
23 the same responsibilities for making that
24 product as if Teva was making this

Page 58

1 product.

2 Q. It's ultimately API going

3 into Teva's finished-dose product, right?

4 A. Not exactly. This is where

5 I wanted to set the clarification.

6 Because when Teva contracts

7 with an API supplier to make API for

8 Teva, that API is actually owned by the

9 API supplier. It's not -- it's not a

10 product that is owned by Teva.

11 And this is why I think it's

12 important to make this distinction.

13 Because that API supplier is solely

14 responsible for his product versus when

15 you are engaging contract manufacturing

16 for Teva within the strict definition, as

17 I understand it, then you're making a

18 Teva product for Teva, so that Teva's

19 responsibilities for that product are

20 much higher than when Teva says to an API

21 supplier, we want you to make your API

22 for us.

23 Q. Are you saying Teva has no

24 responsibilities for the API that a

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1 contract manufacturer is making for Teva?

2 A. Absolutely not. That's not

3 correct.

4 Q. Right. Because we looked at

5 the responsibilities of Teva here in

6 Section 5.2, and there's a number of

7 things that Teva requires itself to have

8 responsibilities for vis-à-vis a contract

9 manufacturer, including one for API,

10 right?

11 MS. LOCKARD: Objection.

12 Form. It misstates his testimony.

13 MR. STANOCH: You can

14 answer, sir.

15 THE WITNESS: So what I'm

16 saying is the expectations are

17 going to be the same. What I'm --

18 what I'm -- we don't see a

19 difference between the GMP

20 expectations that we're setting

21 for the API manufacturer as we

22 would expect for a contract

23 manufacturer.

24 What I'm saying is that the

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1 difference is that when that API

2 supplier makes product for us, our

3 responsibility is to ensure that

4 they perform the activities for us

5 in accordance with GMPs.

6 But the product belongs to

7 them, so they also bear a high

8 degree of responsibility for, you

9 know, engaging in activities that

10 are in compliance with

11 expectations.

12 It's not our product, that's

13 the only difference that I'm

14 making.

15 BY MR. STANOCH:

16 Q. Right. But Teva does take

17 possession of the API product from the

18 contract manufacturer after it's made,

19 right?

20 A. Absolutely.

21 Q. Right. And at least at that

22 point, as soon as it takes possession of

23 it, then it's fully Teva's

24 responsibility, wouldn't you say?

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1 A. It is correct.

2 But let me explain that once

3 that product has been manufactured,

4 tested and released by the API supplier,

5 Teva takes responsibility for ensuring

6 also that, you know, it received that

7 product in accordance with Teva

8 expectations, which is, there is going to

9 be an incoming inspection, there's going

10 to be testing of that product, there's

11 going to be a -- internal certification

12 by Teva that the receipt of that product

13 is in accordance with Teva requirements.

14 Q. And we looked at this policy

15 in Section 5.2.2, in terms of Teva's

16 responsibilities vis-à-vis contract

17 manufacturers.

18 And one is to make sure the

19 contract manufacturers, say that

20 manufacture API, operates under

21 appropriate CGMP conditions, right?

22 A. Yes. And we do look for

23 that, yes.

24 Q. As well as the obligation to

<p>Page 62</p> <p>1 make sure a contract API manufacturer 2 uses processes and test methods that are 3 adequately validated, correct? 4 A. That is correct. 5 Q. And, ultimately, about -- 6 when you believe the -- an API made by a 7 contract API manufacturer is in the 8 possession of the manufacturer or Teva, 9 ultimately when the product is sold with 10 that API in it, it's clearly Teva's 11 responsibility for that product; yes? 12 MS. LOCKARD: Objection. 13 Form. It's confusing. You're 14 confusing contract manufacturers 15 and API suppliers. 16 MR. STANOCH: You can 17 answer. 18 THE WITNESS: So Teva's 19 responsibility for the finished 20 product includes the API, it 21 includes the excipients, and it 22 includes ensuring that the 23 manufacturing process and the 24 testing activities and anything</p> <p>Page 63</p> <p>1 that is associated with ensuring 2 the safety, quality and efficacy 3 and purity of that product, that 4 those -- those expectations are 5 set; not just for the API but for 6 everything. 7 BY MR. STANOCH: 8 Q. Understood. 9 And back in the requirements 10 section, Subsection 5.1.2, the second 11 requirement was the binding, legal 12 quality agreement with Teva, right? 13 Do you see that? 14 A. Yes. 15 Q. And that agreement, in your 16 experience, would spell out certain 17 contractual responsibilities vis-à-vis 18 the manufacture of, say, API that Teva is 19 purchasing, correct? 20 A. Can you repeat the question, 21 please? 22 MR. STANOCH: Amanda, could 23 you read that back? I'm sorry. 24 - - -</p>	<p>Page 64</p> <p>1 (Whereupon, the court 2 reporter read the following part 3 of the record: 4 "Question: And that 5 agreement, in your experience, 6 would spell out certain 7 contractual responsibilities 8 vis-à-vis the manufacture of, say, 9 API that Teva is purchasing, 10 correct?") 11 - - - 12 THE WITNESS: If there is an 13 agreement, that is correct. 14 BY MR. STANOCH: 15 Q. You said "if there is an 16 agreement." 17 I mean, it's a requirement, 18 under the Corporate Standard 0046, for 19 there to be a binding, legal quality 20 agreement with Teva and the contract 21 manufacturer, correct? 22 MS. LOCKARD: Objection. 23 Form. Conflating two issues here. 24 He's explained this.</p> <p>Page 65</p> <p>1 Go ahead. 2 THE WITNESS: Yeah, again, I 3 want to clarify that Section 4 5.1.2, from my understanding, is 5 exclusive for contract 6 manufacturing activities. 7 That means Teva is asking 8 the contract manufacturer to 9 manufacture a Teva product for 10 Teva, where Teva's responsibility 11 is so complete that a binding, 12 legal agreement helps -- legal 13 quality agreement helps Teva to 14 ensure that it can monitor pretty 15 much every single activity that it 16 could monitor if Teva was 17 manufacturing that product. 18 BY MR. STANOCH: 19 Q. So you're saying that Teva 20 doesn't need a quality agreement with an 21 API manufacturer? That's what you're 22 saying, isn't it? 23 A. That is not what I'm saying. 24 What I'm saying is that there are</p>
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<p style="text-align: right;">Page 66</p> <p>1 instances where a quality agreement for 2 non-contract manufacturing activities may 3 or may not exist. And there are a number 4 of reasons for that. 5 One of those reasons would 6 include that the supplier may choose not 7 to engage in a quality agreement for 8 different reasons. 9 Q. Right. And you're saying 10 this because you know there's no quality 11 agreement between Teva's Jerusalem 12 facility and Mylan that was supplying 13 valsartan API to Teva, right? 14 MS. LOCKARD: Objection to 15 form. 16 BY MR. STANOCH: 17 Q. Sir, do you know whether or 18 not there is a quality agreement between 19 Teva's Jerusalem facility and Mylan's 20 Unit 8 for valsartan API? 21 A. I know there was no quality 22 agreement. 23 Q. Right. None existed, did 24 it?</p>	<p style="text-align: right;">Page 68</p> <p>1 have any quality agreement with a 2 supplier of valsartan API? 3 A. Can you tell me the time 4 period? Because I think that today Teva 5 does -- and this is one thing that when I 6 was at Teva, it was activity that I 7 wanted to ensure that we could, you know, 8 develop and transition into, with the 9 understanding still that obtaining a 10 quality agreement with a supplier may or 11 may not always be possible. 12 Q. Well, you tell -- you tell 13 me your understanding of the time 14 periods. 15 Do you recall whether Teva 16 ever had any such policy? 17 A. I don't think that that was 18 a policy, if it exists, that was clearly 19 defined. So I don't -- the answer would 20 be probably not, no. 21 Q. And just so we're clear on 22 your testimony for the jury, you're 23 saying that in the instance of Mylan 24 supply of valsartan API to Teva's</p>
<p style="text-align: right;">Page 67</p> <p>1 A. Correct. 2 Q. So you're telling me that 3 notwithstanding the lack of that 4 agreement, that it was not a breach of 5 this requirement because it wasn't 6 required under Corporate Policy 0046? 7 A. Once again, I'd like to 8 clarify. 9 When I read this section, 10 the expectation for quality agreement in 11 this case is for a contract manufacturing 12 facility. 13 Q. And you're saying that in 14 that -- in the substance of Mylan's 15 supply of API -- strike that. 16 You're saying in the 17 instance of Mylan's supply of valsartan 18 API to Teva's Jerusalem facility, that 19 was not a contract manufacturing 20 activity? 21 A. That's exactly what I'm 22 saying. 23 Q. So you're saying, then, that 24 Teva had no policy that required it to</p>	<p style="text-align: right;">Page 69</p> <p>1 Jerusalem facility, Mylan was not acting 2 as a contract manufacturer, which is a 3 separate company that provides drug 4 product or processes, a drug product or 5 drug substance in accordance with 6 predetermined specifications; you're 7 saying it was not a contract 8 manufacturer? 9 A. That's what I'm saying. 10 Q. Are you aware of any 11 agreement between Teva's Jerusalem 12 facility and Mylan's Unit 8 concerning 13 Teva's purchase of valsartan API from 14 Mylan's Unit 8? 15 MS. LOCKARD: Objection. 16 Asked and answered. 17 MR. STANOCH: You can 18 answer. 19 THE WITNESS: I am sure that 20 there is some kind of a supply 21 agreement between Teva and Mylan. 22 I'm not familiar with it. 23 But it is typical for the 24 purchase of product to include a</p>

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1 supplier agreement or
2 understanding between the two
3 companies.
4 BY MR. STANOCH:
5 Q. Right. It is typical, isn't
6 it, right?
7 A. Yes.
8 Q. And you spent, what, 50
9 hours looking at documents to prepare for
10 today, yes?
11 A. That is correct.
12 Q. And you did not see any
13 instance of such an agreement, did you?
14 MS. LOCKARD: Objection.
15 Vague.
16 MR. STANOCH: You can
17 answer.
18 THE WITNESS: Of what type
19 of agreement are you talking?
20 BY MR. STANOCH:
21 Q. In your 50 hours of
22 preparation for today's deposition, did
23 you see any quality agreement concerning
24 Teva Jerusalem's purchase of valsartan

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1 API from Mylan's Unit 8?
2 A. Quality agreement, no.
3 Q. Did you see any agreement
4 between Teva, for the purchase of
5 valsartan API from Mylan Unit 8, for its
6 Jerusalem facility?
7 A. I don't recall.
8 Q. And you know that the
9 Jerusalem facility was the one that was
10 processing Mylan valsartan API into
11 finished dose for sale into the U.S.
12 market, right?
13 A. I'm well aware of that, yes.
14 MR. STANOCH: I'm going to
15 mark the next exhibit, sir.
16 This is Exhibit-136. For
17 the record, it's Bates ending
18 00042539.
19 - - -
20 (Whereupon, Exhibit
21 Teva-136, TEVA-MDL2875-00042539,
22 Teva Corporate Standards
23 CORP-0175, was marked for
24 identification.)

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1 - - -
2 BY MR. STANOCH:
3 Q. Tell me when you're able to
4 access that document, sir.
5 A. Yes.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 A. That is correct.
21 Q. And GXP, that refers to
22 either GMP or GCP, GLP or GDP, as
23 appropriate, right?
24 A. That would be correct.

Page 73

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 74

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. Right. So that -- right.
12 So this would include an arrangement
13 between Teva's Jerusalem facility and
14 Mylan's Unit 8 for the purchase of
15 valsartan API, yes?
16 MS. LOCKARD: Objection.
17 Form.
18 MR. STANOCH: You can
19 answer.
20 THE WITNESS: Can you repeat
21 the question, please?
22 BY MR. STANOCH:
23 Q. This policy would cover the
24 situation of Teva's Jerusalem facility
procuring API from Mylan's Unit 8,

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1 correct?
2 A. That would be correct.
3 MS. LOCKARD: Same
4 objection.
5 BY MR. STANOCH:
6 Q. Right. And one of the
7 requirements of Teva's own policies was
8 to -- shall prepare and fully approve a
9 quality technical agreement for that
10 purchase of valsartan API from Mylan Unit
11 8, correct?
12 MS. LOCKARD: Objection.
13 Form. Misstates the document.
14 MR. STANOCH: You can
15 answer.
16 THE WITNESS: Can you repeat
17 the question, please?
18 MR. STANOCH: Amanda, if you
19 would.
20 - - -
21 (Whereupon, the court
22 reporter read the following part
23 of the record:
24 "Question: And one of the

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1 requirements of Teva's own
2 policies was to -- shall prepare
3 and fully approve a quality
4 technical agreement for that
5 purchase of valsartan API from
6 Mylan Unit 8, correct?")
7 - - -
8 THE WITNESS: Yes.
9 BY MR. STANOCH:
10 Q. So as far as you know,
11 because you never could see it or find
12 any agreement between Teva and Mylan's
13 Unit 8 for the -- strike that.
14 So this requirement, as
15 reflected in Teva Policy Corp. 0175, as
16 far as you know, was not fulfilled,
17 because no agreement exists that you know
18 of, right?
19 MS. LOCKARD: Objection.
20 Form.
21 THE WITNESS: We are aware
22 that there was no quality
23 agreement.
24 BY MR. STANOCH:

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1 Q. Right. So this requirement,
2 5.2, to have such an agreement, was not
3 met, correct?
4 A. I don't know if it was not
5 met, in terms of whether Jerusalem, at
6 one point, made an effort to contact
7 Mylan and to pursue the generation of a
8 quality agreement.
9 As I indicated to you
10 before, there are instances where you
11 pursue a quality agreement and the
12 supplier may choose not to accept it.
13 Q. Sitting here today, can you
14 say whether Requirement 5.2 was met for
15 Teva Jerusalem's purchase of valsartan
16 API from Mylan's Unit 8?
17 A. Let me go back to the
18 document, please.
19 Repeat the question, please.
20 MR. STANOCH: Madam Court
21 Reporter, I'm sorry, if you could.
22 - - -
23 (Whereupon, the court
24 reporter read the following part

Page 78

1 of the record:
2 "Question: Sitting here
3 today, can you say whether
4 requirement 5.2 was met for Teva
5 Jerusalem's purchase of valsartan
6 API from Mylan's Unit 8?")
7 - - -
8 THE WITNESS: I would say
9 that besides the fact that the
10 quality agreement expectation in
11 this case may not have been met,
12 any other considerations that were
13 necessary to ensure that the
14 quality of product that we were
15 going to receive from Mylan, those
16 other expectations were met.
17 BY MR. STANOCH:
18 Q. I'm only asking about the
19 requirement reflected in 5.2.
20 As far as you know, this
21 requirement was not met, correct?
22 A. Correct.
23 Q. And if you flip to Section
24 5.12, maintenance of documents.

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1 Tell me when you're there.
2 A. Yes.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 80

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 Q. Do you recall who the head
7 of quality assurance at Teva Jerusalem
8 was during your tenure at Teva?
9 A. There were a number of
10 changes of personnel. So at this moment,
11 I cannot exactly tell you who that person
12 was.
13 Q. Even though it might not be
14 comprehensive, tell me anyone who you
15 think held that role during your tenure
16 at Teva.
17 A. Leron is -- she took over, I
18 think it was Karen -- Karen -- I'm trying
19 to remember the names now, so my
20 apologies for that.
21 But I can visualize their
22 faces. So we could -- we could get this
23 information later on for you.
24 Q. That's fine, sir. If you

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1 don't recall right now, that's fine.
2 Look, if later in the day
3 you do, feel free to interject and say,
4 hey, I remember their name. That's all.
5 A. Yep. Okay.
6 Q. I appreciate that.
7 Sticking with this
8 section -- and then maybe we can take a
9 break soon, because we've been going over
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 Did I read that right?
19 A. Yes, that is correct.
20 Q. Are you familiar with Teva's
21 global QTA database?
22 A. I'm familiar with its
23 existence. But I did not look at it
24 during my tenure there.

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[REDACTED]

Page 84

1 agreement.

2 MR. STANOCH: Sir, we've

3 been going for a little over an

4 hour. I'm happy to keep going,

5 but if you'd like a few-minute

6 break, let me know.

7 MS. LOCKARD: A break would

8 be good.

9 MR. STANOCH: Okay. Let's

10 go off the record.

11 THE WITNESS: I appreciate

12 it.

13 VIDEO TECHNICIAN: The time

14 is 9:15 a.m. Going off the

15 record.

16 - - -

17 (Whereupon, a brief recess

18 was taken.)

19 - - -

20 VIDEO TECHNICIAN: The time

21 is 9:28 a.m. Back on the record.

22 BY MR. STANOCH:

23 Q. Welcome back, Mr. Barreto.

24 A. Thank you.

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1 A. Correct. Correct.

2 Q. So if there was a quality

3 technical agreement between Teva

4 Jerusalem and Mylan Unit 8 for the

5 purchase of valsartan API, it would have

6 been someone within your group to ensure

7 that that agreement made its way into the

8 Teva global QTA database?

9 MS. LOCKARD: Objection.

10 Form.

11 THE WITNESS: If it was

12 under my or another group --

13 quality group responsibility, yes.

14 BY MR. STANOCH:

15 Q. And sitting here today, you

16 don't know whether any agreement between

17 Teva Jerusalem and Mylan Unit 8

18 encompassing the purchase of valsartan

19 API exists in the Teva global QTA

20 database, correct?

21 MS. LOCKARD: Objection.

22 Asked and answered.

23 THE WITNESS: We have

24 confirmed that there is no such

Page 85

1 Q. You're familiar with Teva's

2 operating procedures concerning data

3 integrity?

4 A. Yes, I am.

5 Q. And I'll put the policy in

6 front of you in a moment, sir.

7 But just generally, if you

8 could tell us what data integrity means?

9 A. So data integrity is about

10 companies ensuring that they produce

11 documentation, that it meets what's

12 called the ALCOA expectation. So for the

13 most part, to summarize, the data has to

14 be reliable, has to be trustworthy, has

15 to be correct.

16 Q. And data integrity, in part,

17 is subject to GMP regulations, correct?

18 A. It is correct.

19 MR. STANOCH: I'm going to

20 mark the next exhibit, sir,

21 Teva-137.

22 - - -

23 (Whereupon, Exhibit

24 Teva-137, TEVA-MDL2875-00586753,

Page 86

1 Teva Corporate Standard,
2 Corp-0896, was marked for
3 identification.)
4 - - -
5 MR. STANOCH: I'll state for
6 the record it's Bates beginning --
7 or ending 00586753.
8 BY MR. STANOCH:
9 Q. Tell me when you can pull
10 that up, sir.
11 A. I do -- I have it.
12 Q. This is Corporate Standard
13 0896?
14 A. That is correct.

[REDACTED]

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[REDACTED]

Page 88

[REDACTED]

Page 89

[REDACTED]

Page 90

[REDACTED]

Page 92

[REDACTED]

13 MS. LOCKARD: Objection.
14 Asked and answered.
15 MR. STANOCH: You can
16 answer.
17 THE WITNESS: So as I
18 indicated, that's -- the policy
19 proposes that that be the case,
20 that we do that through a quality
21 agreement.
22 There are instances where
23 that expectation from the policy
24 cannot be fulfilled, but --

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[REDACTED]

22 So I don't know the
23 specifics in this case. But the absence
24 of a quality agreement does not preclude

Page 93

[REDACTED]

Page 94

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 MR. STANOCH: I'm going to
8 move to strike, sir, because it's
9 not responsive to the question.
10 BY MR. STANOCH:
11 Q. The question is, Teva's own
12 policy, does it say that it would be nice
13 to have or propose to have a quality
14 agreement with a third-party contractor?
15 MS. LOCKARD: Objection.
16 Asked and answered.
17 Argumentative.
18 And I believe the court has
19 said it's inappropriate to move to
20 strike the witness's answer.
21 MR. STANOCH: You can
22 answer.
23 MS. LOCKARD: The judgment
24 actually addressed that.

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1 MR. STANOCH: You can
2 answer.
3 THE WITNESS: So the policy
4 is an expectation that is set by
5 Teva. And what I'm trying to say
6 is that there will be instances
7 where the expectations of the
8 policy cannot be met. And that,
9 in my opinion, does not
10 necessarily represent that the
11 objectives and expectations of the
12 policy have not been met through
13 other means.
14 BY MR. STANOCH:
15 Q. Well, again, in the instance
16 of Teva Jerusalem sourcing valsartan API
17 from Mylan's Unit 8, the expectation that
18 the activity of Mylan Unit 8 must be
19 controlled through a quality agreement is
20 not met, to your knowledge, right?
21 A. The expectations of the
22 policy, no, they have not been met.
23 However, the expectations
24 that you would have from a quality

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1 agreement will have been met.
2 Q. Going back to the last
3 exhibit, sir, it was --
4 A. Are you speaking about the
5 data integrity --
6 Q. No, sir, I'm sorry. Let me
7 tell you the exhibit number.
8 It was the one that -- for
9 Corporate Policy 0046. It was the one
10 with the e-mail that attached the
11 corporate policy concerning outsourced
12 activities, contract manufacture and
13 analysis.
14 MS. LOCKARD: Exhibit-135.
15 MR. STANOCH: Thank you,
16 counsel.
17 THE WITNESS: I'm just
18 opening it.
19 Yes, sir.
20 BY MR. STANOCH:
21 Q. Sure. Are you there?
22 A. Yes, sir.
23 Q. We had spoken a little bit
24 about Subsection 5.2.4, Change Control.

Page 97

1 Do you recall that
2 subsection?
3 A. Yes, I do.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. Are you aware of any change
12 control procedure documented between Teva
13 Jerusalem, or Teva generally, and Mylan
14 Unit 8 relating to the manufacture and
15 purchase of valsartan API?
16 A. Again, I think the
17 expectations of this section is -- speaks
18 more about the contract manufacturing
19 facility and goes back to what I think is
20 important -- an important distinction
21 that has to be made.
22 So in the event that a
23 contract manufacturing facility is
24 manufacturing a Teva product for Teva,

<p style="text-align: right;">Page 98</p> <p>1 that change control procedure is 2 extremely important, because the 3 execution of any changes from that 4 contractor would affect the expectations 5 of a Teva product. 6 So that -- this is the 7 reason why it is so specific to contract 8 manufacturing facilities. 9 So in the case of a 10 third-party supplier of an activity, the 11 expectation is that the change control 12 procedure has to be controlled by the 13 contractor because they are the owners of 14 the product. 15 Q. I think what you're saying 16 is that -- well, let's be specific. 17 So you know that -- we 18 already established Teva Jerusalem was 19 purchasing valsartan API from Mylan Unit 20 8, right? 21 A. Yes. 22 Q. And we know that the -- the 23 Malta facility was purchasing valsartan 24 API from Zhejiang Huahai Pharmaceuticals,</p>	<p style="text-align: right;">Page 100</p> <p>1 THE WITNESS: I disagree. 2 MS. LOCKARD: Form. 3 Misstates the document. 4 MR. STANOCH: You can 5 answer. 6 THE WITNESS: I disagree 7 totally with this. 8 Because in this industry, if 9 you were to have a change control 10 procedure between a third party 11 and a purchaser of the product 12 from that third party, that is not 13 industry practice. 14 Again, I reaffirm on my 15 position that definitely a change 16 control procedure between Teva and 17 the contractor, being a contract 18 manufacturing facility for Teva, 19 that makes complete sense. 20 A change control procedure 21 between the third party and Teva, 22 that would -- that would not be 23 something that I would expect to 24 exist because that would not be</p>
<p style="text-align: right;">Page 99</p> <p>1 or ZHP, correct? 2 A. That's correct. 3 Q. Right. So in those 4 instances, the contractor, as you 5 referred to it, would be ZHP for the 6 Malta facility, and Mylan for the Teva 7 Jerusalem purchases, correct? 8 A. A contractor within the 9 terms of -- not a contract manufacturer 10 for Teva, but contractor in terms of the 11 contractor being a supplier of its own 12 API. That's where I want to make the 13 distinction. 14 Q. Got it. 15 And this section we're 16 looking at, change control, it says 17 contractor, right? 18 A. That's what it says, yes. 19 Q. Right. It's not saying 20 contract manufacturer, right? This is 21 saying contractor, so that would include 22 ZHP and Mylan in the context of the 23 valsartan API, correct? 24 MS. LOCKARD: Objection.</p>	<p style="text-align: right;">Page 101</p> <p>1 possible from a practical 2 perspective, and it's not what, 3 you know -- it's not industry 4 practice. 5 BY MR. STANOCH: 6 Q. Let's get the nomenclature 7 right for the rest of the day. 8 Specifically with respect to 9 ZHP supply of valsartan API to the Malta 10 facility, you're saying ZHP should be 11 called a third-party supplier? 12 A. That's what I'm saying. 13 Q. Okay. And same with Mylan 14 Unit 8 supplying API to the Teva 15 Jerusalem, correct? 16 A. That is what I'm saying. 17 Q. Okay. Regardless of whether 18 ZHP and Mylan's Unit 8 were contractors 19 or third-party suppliers, was it your 20 understanding that any manufacturing 21 change of valsartan API by ZHP or Mylan 22 Unit 8 would have had to have been shared 23 with Teva beforehand? 24 A. I disagree. The term "any,"</p>

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1 it would be an all-encompassing
2 expectation which goes against what I
3 just said before.
4 What I do expect, that any
5 significant change that would have an
6 impact on the composition, specifications
7 and on my finished drug product, then I
8 would expect that supplier to notify that
9 information to -- to us at Teva.
10 Q. Are you aware of whether ZHP
11 ever informed Teva, or the legacy Actavis
12 Malta facility, prior to integration, of
13 any changes to the manufacture of the
14 valsartan API that ZHP was supplying to
15 Malta?
16 A. I am.
17 Q. Okay. What are you aware
18 of?
19 A. So there was a change to the
20 manufacturing process from what was
21 called the TEA process to the zinc
22 chloride process.
23 Q. And we will have documents
24 to this effect.

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1 But do you recall when that
2 change was shared with the Malta facility
3 or Actavis generally?
4 A. If I recall well, it was
5 either in 2012 or '13.
6 Q. Do you recall any other
7 manufacturing changes concerning
8 valsartan API that ZHP shared with Teva
9 or the legacy Actavis entity?
10 A. The --
11 MS. LOCKARD: Sorry. I'm
12 just going to object to the extent
13 we're getting outside the scope of
14 the deposition topics. This
15 relates to any other changes other
16 than the one at issue in the
17 notice in the litigation.
18 MR. STANOCH: Well, counsel,
19 he identified a manufacturing
20 process concerning TEA to zinc
21 chloride. So I'm just asking any
22 others that he recalls.
23 MS. LOCKARD: Okay. And
24 that's fine and fair. I mean, you

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1 can ask him.
2 I just want to make clear
3 that, you know, we do not
4 interpret any -- any and all
5 changes by ZHP over the course of
6 time to be encompassed by the
7 notice.
8 But you can ask him. If he
9 has personal knowledge, he can
10 answer.
11 BY MR. STANOCH:
12 Q. What other changes --
13 A. I have no knowledge.
14 Q. You have no personal
15 knowledge; is that correct, sir?
16 Correct?
17 A. Nope. Nope. Correct.
18 MR. STANOCH: Counsel, what
19 process changes, then, are you
20 saying are within the notice?
21 Just, if you want to tell me?
22 Manufacturing? What else? And
23 I'll use those phrases instead of
24 "any."

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1 MS. LOCKARD: Okay. So you
2 want me to pull up the notice
3 or --
4 MR. STANOCH: It was your
5 objection, counsel. You said any
6 process is outside the notice. So
7 I just want to know what change is
8 within the notice, under your
9 interpretation. That's all.
10 MS. LOCKARD: Okay. The
11 process change that he just
12 described with respect to the TEA
13 process, you know, anything that
14 relates to the change in the
15 formation of triethylamine.
16 You know, the underlying
17 root cause process, as outlined in
18 the notice, you know, that was
19 basis for the root cause that ZHP
20 provided to us and that Mr.
21 Barreto oversaw on Teva's end.
22 My point -- I'm not trying
23 to be difficult. But I'm saying
24 you're opening up to any and all

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1 process changes ever in all time,
2 whether or not they relate to, you
3 know, the creation of nitrosamines
4 or not. I don't know if there are
5 some minor process change that
6 exists out there in the
7 documentation of Teva and ZHP.
8 But that's not the focus of
9 our deposition today. And that's
10 not the focus of the root cause
11 process and it's not the focus of
12 the litigation.
13 So I don't have knowledge
14 and information about all the
15 other potential process changes or
16 even if there were other process
17 changes. And we haven't prepped
18 Mr. Barreto on that. That's my
19 only point.
20 MR. STANOCH: Thank you,
21 counsel.
22 BY MR. STANOCH:
23 Q. Mr. Barreto, other than the
24 manufacturing process change from the TEA

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1 process to the zinc chloride process, are
2 you aware of any other ZHP manufacturing
3 changes pertinent to its valsartan API?
4 A. I'm not aware of any other
5 changes.
6 Q. I believe you said you
7 understand that change was disclosed
8 to -- I guess it would be, what, legacy
9 Actavis at the time?
10 A. It would -- that would be my
11 understanding.
12 Q. Was the change to -- the
13 manufacturing change by ZHP from the TEA
14 process to the zinc chloride process ever
15 shared with Teva, to your knowledge?
16 A. Yes. And it was shared
17 through a communication to Teva, number
18 one. And it was also shared with Teva
19 through the performance of an audit by
20 our corporate auditors who visited the
21 site.
22 Q. Do you recall when the
23 manufacturing process change by ZHP from
24 the TEA process to the zinc chloride

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1 process was first --
2 A. I think --
3 Q. -- shared with Teva?
4 A. I'm sorry.
5 I think it was around 2012.
6 Q. And you mentioned it might
7 have been discussed as part of a Teva
8 audit of ZHP as well?
9 A. That is correct.
10 Q. Do you recall the year of
11 that audit you're thinking of?
12 A. I want to remember the year.
13 But, again, it would have been either '12
14 or '13. It's just right around the time
15 when we became aware of that change and
16 the decision was made to audit.
17 Q. Are you aware of any
18 manufacturing changes by Mylan's Unit 8
19 concerning valsartan API that Mylan ever
20 shared with Teva?
21 A. Yes.
22 Q. Which --
23 A. Again, I'd like to -- sorry.
24 I'd like to clarify.

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1 I'm not aware of all the
2 manufacturing changes, but I'm aware of
3 one manufacturing change.
4 Q. To the extent you're aware
5 of -- just tell me what you're aware of.
6 I understand.
7 A. I'm aware that there was a
8 change from what was called the VST
9 process to the VAA process.
10 Q. And that change was post the
11 recalls that are underlying this
12 litigation, right?
13 A. If I recall well, yes, that
14 was intended to be post recall.
15 Q. And we'll get into that
16 later, when we go through the chronology
17 a little bit more.
18 But that was, I think,
19 what's referred to as sort of an
20 optimized process; is that right?
21 A. That is correct.
22 Q. And that was Mylan's effort
23 to address the nitrosamine impurities
24 that had been discovered in its valsartan

<p>Page 110</p> <p>1 API, right?</p> <p>2 A. That is correct.</p> <p>3 Q. So prior to the recalls</p> <p>4 concerning nitrosamines in 2018, are you</p> <p>5 aware of any manufacturing process</p> <p>6 changes that Mylan shared with Teva?</p> <p>7 A. Prior to that, no, I'm not</p> <p>8 aware.</p> <p>9 Q. Who at legacy Actavis would</p> <p>10 be responsible for evaluating the</p> <p>11 manufacturing process change in 2012 by</p> <p>12 ZHP from the TEA process to the zinc</p> <p>13 chloride process?</p> <p>14 A. So there were a number of</p> <p>15 different evaluations that were</p> <p>16 performed. They start at the -- there's</p> <p>17 RMV organization work, there is a site</p> <p>18 work that is performed, a number of</p> <p>19 studies and experiments that are</p> <p>20 conducted.</p> <p>21 And then, of course, later</p> <p>22 on, you've -- all of this information</p> <p>23 that is generated is picked up by the</p> <p>24 regulatory organization who has the</p>	<p>Page 112</p> <p>1 that were in place were the analytical</p> <p>2 test methods that were authorized and</p> <p>3 approved by the regulatory authorities.</p> <p>4 Q. Well, when you say "approved</p> <p>5 by the regulatory authorities," that</p> <p>6 would be, what, the DMF? Or what are you</p> <p>7 referring to?</p> <p>8 A. I'm referring to the</p> <p>9 analytical test methods that are used to</p> <p>10 confirm and certify the specifications</p> <p>11 set for the product. These analytical</p> <p>12 test methods are USB test methods, so you</p> <p>13 are expected and required to perform</p> <p>14 those test methods on the products.</p> <p>15 Q. You mentioned nitrosamine.</p> <p>16 So I guess, number one,</p> <p>17 you're not aware of any testing that</p> <p>18 legacy Actavis did in 2012 of the</p> <p>19 valsartan API process change by ZHP that</p> <p>20 would have detected nitrosamines, are</p> <p>21 you?</p> <p>22 A. The analytical test methods</p> <p>23 that were used at the time to test the</p> <p>24 product from ZHP were intended to and</p>
<p>Page 111</p> <p>1 responsibility for submitting an ANDA</p> <p>2 supplement.</p> <p>3 Q. Do you recall the specific</p> <p>4 departments or persons at legacy Actavis</p> <p>5 who were involved in that evaluation or</p> <p>6 effort?</p> <p>7 A. There were various</p> <p>8 organizations from within the local</p> <p>9 facility, quality assurance, R&D,</p> <p>10 technical operations. These different</p> <p>11 organizations were involved.</p> <p>12 Q. In your review of materials</p> <p>13 concerning legacy Actavis's evaluation of</p> <p>14 the ZHP manufacturing process change, did</p> <p>15 you see anything in which legacy Actavis</p> <p>16 conducted any gas chromatography or mass</p> <p>17 spectrometry testing on the valsartan</p> <p>18 API?</p> <p>19 A. No. And they would not have</p> <p>20 conducted anything around gas</p> <p>21 chromatography specific for, I think,</p> <p>22 what the concern is with respect to</p> <p>23 valsartan.</p> <p>24 The analytical test methods</p>	<p>Page 113</p> <p>1 designed to detect the impurities and the</p> <p>2 active ingredient that were deemed to be</p> <p>3 present in the product.</p> <p>4 In 2012, there was no reason</p> <p>5 to believe that there were nitrosamines</p> <p>6 present in the ZHP process.</p> <p>7 Q. Well, there were no</p> <p>8 nitrosamines identified as an impurity in</p> <p>9 the DMF submitted by ZHP, right?</p> <p>10 A. Sorry, can you repeat the</p> <p>11 question?</p> <p>12 Q. There were no -- there were</p> <p>13 no nitrosamines impurities identified in</p> <p>14 the DMF submitted by ZHP, right?</p> <p>15 A. That would be my</p> <p>16 understanding.</p> <p>17 Q. So when you said Actavis</p> <p>18 would have just done the testing that --</p> <p>19 or the methods intended, there would not</p> <p>20 have been a specific test done for</p> <p>21 nitrosamines, at that time, when Actavis</p> <p>22 was evaluating the ZHP manufacturing</p> <p>23 process change from the TEA to the zinc</p> <p>24 chloride process?</p>

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1 A. That is correct. There
2 would be no test method designed to look
3 for something that we didn't expect that
4 would be present.
5 Q. Well, that was not
6 identified by ZHP to Teva, or anyone
7 else, as being present; is that fair?
8 A. That is correct.
9 Q. And nitrosamines aside,
10 you're not aware of any use of gas
11 chromatography at all by Actavis when it
12 was evaluating the manufacturing process
13 change by ZHP in 2012 from the TEA
14 process to the zinc chloride process,
15 right?
16 A. I'm not aware of any testing
17 that was done using GC-MS.
18 Q. In terms of Teva itself, you
19 mentioned that Teva was made aware of the
20 change by ZHP in 2012 or 2013, right?
21 A. Yes.
22 Q. Are you aware of any tests
23 that Teva performed in evaluating the ZHP
24 manufacturing change from the TEA to the

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1 zinc chloride process that could detect
2 nitrosamines in the valsartan API?
3 A. No.
4 Q. Are you aware of whether
5 Teva performed any gas chromatography
6 testing in its evaluation of the ZHP
7 manufacturing process change from the TEA
8 process to the zinc chloride process?
9 A. No, because that would not
10 have been expected.
11 Q. Because -- it would not be
12 expected because it was not on the
13 specifications in the DMF on file by ZHP?
14 A. Or in the NDA.
15 Q. Correct.
16 A. I'm sorry, ANDA.
17 Q. That would be Teva's ANDA,
18 correct?
19 A. Correct.
20 Q. Because Teva's ANDA for any
21 valsartan product would refer to the DMF
22 submitted by ZHP in this instance,
23 correct?
24 A. That is correct.

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1 Q. And the testing parameters
2 or potential impurities that Teva would
3 be testing for would be only those that
4 ZHP had identified in the DMF to which
5 Teva's ANDA is referring?
6 A. That is correct.
7 And the analytical test
8 methods that ZHP was using at the time
9 were also USB analytical test methods.
10 Q. I'm going to fast-forward to
11 the 2018 time period a little bit, sir,
12 just to orient you, okay?
13 A. Okay.
14 Q. And I understand there came
15 a time that Teva issued a field alert
16 concerning valsartan products; is that
17 right?
18 A. That is correct.
19 Q. And in June of 2018, did you
20 have any responsibilities concerning the
21 issuance of field alerts?
22 A. I did.
23 Q. What were the scope of your
24 responsibilities at that time?

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1 A. So I was designated to be
2 the main contact person, from a corporate
3 perspective, with respect to receiving,
4 reviewing and approving the issuance of
5 field alert reports to be submitted to
6 the FDA.
7 Q. And so we're clear, can you
8 just tell us what a field report is?
9 A. So a field alert report is
10 predicated on the fundamentals that
11 whenever a company comes to information
12 that indicates that there is a potential
13 quality/safety issue associated with a
14 product in distribution, even in the
15 absence of certain information, the -- it
16 is the responsibility of that company to
17 notify the U.S. Food and Drug
18 Administration of the initial issue.
19 Q. I'm going to try to pull up
20 the next exhibit, sir. One moment.
21 MR. STANOCH: This exhibit,
22 I think, was previously marked as
23 Teva Exhibit-5.
24 You should be able to see

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1 it, I think, sir.
2 THE WITNESS: I'm
3 refreshing.
4 MR. STANOCH: And, counsel,
5 I was trying to avoid double
6 marking something we've marked
7 before. That's all. Thank you
8 for your patience.
9 THE WITNESS: So, yes, I
10 have it.
11 BY MR. STANOCH:
12 Q. Great. And this exhibit
13 previously marked as Teva Exhibit-5, it's
14 a cover e-mail from Constance Truemper
15 dated July 3rd, 2018, and then it
16 attaches what appears to be the field
17 alert.
18 Do you see that?
19 A. Yes, I do.
20 Q. And if you can just turn to
21 the field alert, this is the field alert
22 that Teva submitted concerning -- strike
23 that.
24 Just tell me, what's the

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1 field alert here?
2 A. So in this case, the field
3 alert, as soon as we became aware and
4 collected information -- sufficient
5 information to put together a report to
6 the agency, we submitted that report to
7 the agency on July 3rd.
8 Q. Right. And it lists here a
9 number of the form information that Teva
10 filled out, right?
11 A. That is correct.
12 Q. And it identifies, I guess,
13 the Malta facility as the facility at
14 issue, right?
15 A. That is correct.
16 Q. It identifies the NDCs for
17 the valsartan products that the Malta
18 facility was selling into the United
19 States that incorporated valsartan API
20 from ZHP?
21 A. That's what Section 4 says,
22 yes.
23 Q. And then Section 9, it's --
24 the format is the date when notified

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1 about problems, or when problems first
2 became known to the application holder.
[REDACTED]

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[REDACTED]

9 Q. Was that accurate at the
10 time this was written, to your knowledge?
11 A. At the time, based on the
12 information that we had, we -- we assumed
13 and we decided that we wanted to make
14 sure that all the lots that were
15 manufactured within that time period
16 would be included.
[REDACTED]

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1 Q. In the field report, it said
2 you were notified about -- Teva was
3 notified about the problem, that was Box
4 9, that's what, June 28th, 2018?
5 A. That's when we became aware
6 of the problem, yes.
7 Q. Wasn't Teva aware of the
8 problem earlier than that?
9 A. Excuse me?
10 Q. Wasn't Teva aware of the
11 problem earlier than that?
12 MS. LOCKARD: Object to the
13 form. Vague.
14 THE WITNESS: Prior to that
15 instance, we understand that there
16 was a communication between a
17 supplier and a Teva supply chain
18 organization where there were some
19 preliminary discussions as to
20 whether or not there was a
21 problem.
22 On 6/28, that's when us in
23 the quality organization became
24 aware that -- of this

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1 notification. And that's the
2 point at which we started to now
3 gather all the information,
4 collect all the details that we
5 needed to gather.
6 That was on a Thursday when
7 we started to gather all the
8 details to make a prompt
9 submission to the FDA.
10 BY MR. STANOCH:
11 Q. Well, Teva knew at least a
12 week or so earlier than June 28th about
13 the impurity in the valsartan API, didn't
14 it?
15 A. Teva had -- the supply chain
16 organization, from my understanding, had
17 some preliminary information that
18 indicated that there was an apparent
19 problem with the product.
20 The details -- the more
21 formal details came later on, and that's
22 when we, in the quality organization,
23 came and had together all the details
24 that we needed to now initiate the

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1 process of putting together and releasing
2 a field alert report.
3 Q. So you're saying June 28th
4 is when the quality department, your
5 department, got involved in this issue?
6 A. That is correct.
7 MR. STANOCH: I'm going to
8 mark the next exhibit. One
9 moment.
10 This will be Exhibit-138.
11 - - -
12 (Whereupon, Exhibit
13 Teva-138,
14 TEVA-MDL2875-00495102-5104, 7/6/18
15 E-mail, Drape to Vanderweeen, was
16 marked for identification.)
17 - - -
18 THE WITNESS: I'm trying to
19 refresh.
20 MR. STANOCH: That's fine.
21 Just let me know.
22 And while you're doing that,
23 for the record, it's ending Bates
24 495102.

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1 THE WITNESS: So I have it
2 there, yes.
3 BY MR. STANOCH:
4 Q. Okay. And this appears to
5 be an e-mail chain, topmost ^^ message
6 from an Eric Drape, sent on July 6th,
7 2018; is that right?
8 A. That's what I see here.
9 Q. And then you're copied on at
10 least the first couple of messages there,
11 the top messages, right?
12 A. That is correct.
13 Q. Do you recall this e-mail?
14 A. Vaguely I do, yes.
15 Q. And the original message
16 here is from July 6th, 2018, from a Ms.
17 Eva Wong.
18 Do you see that?
19 A. Yes, I do.
20 Q. It looks like she's
21 e-mailing regulators in Hong Kong,
22 correct?
23 A. That is correct.
24 Q. And it says here in her

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1 signature block she's associate director,
2 APAC commercial quality; is that right?
3 A. Yes, that's right.
4 Q. Was she within your
5 department at the time?
6 A. No. She was in another
7 organization.
8 Q. Okay. And in Ms. Wong's
9 message to the Hong Kong authorities, she
10 writes, in part, On June 20th, 2018, Teva
11 was notified by Zhejiang Huahai that they
12 came to be aware of a previously unknown
13 impurity that may create a risk to
14 patient health and safety and requested
15 Teva to put temporarily on hold the use
16 of all valsartan API immediately.
17 Do you see that?
18 A. I see that.
19 Q. I mean, if Ms. Wong in
20 commercial quality is saying that she was
21 aware of the issue June 20, why did it
22 take until June 28th for you and your
23 group to become aware of it and tell the
24 FDA about it?

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1 MS. LOCKARD: Objection.
2 Form. Compound.
3 MR. STANOCH: You can
4 answer.
5 THE WITNESS: Okay. So from
6 my perspective, I do not know
7 exactly what transpired between
8 the 20th and June 28. So I don't
9 know exactly how that
10 communication did not get in to
11 us.
12 The only thing that I can
13 tell you is that as soon as we
14 became aware of the situation, we
15 took immediate action.
16 BY MR. STANOCH:
17 Q. At this time, Teva had a
18 standard operating procedure concerning
19 field alert reporting, didn't it?
20 A. Can you clarify, please?
21 Q. Sure. In 2018, Teva had a
22 corporate policy concerning field alert
23 reporting, right?
24 A. That is correct. That is

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1 correct.
2 Q. Right. And I can put it in
3 front of you, but does it sound right to
4 you that the policy required Teva to
5 establish and maintain procedures to
6 ensure field alerts are filed with the
7 FDA within three working days of
8 discovery?
9 A. That is correct.
10 Q. Right. So the discovery
11 of -- at least from Ms. Wong's e-mail, it
12 was June 20th, a field alert should have
13 been issued by Teva three days from that
14 date, right?
15 MS. LOCKARD: Objection.
16 Form. Vague.
17 THE WITNESS: My response
18 to -- if we had become aware on
19 June 20th of this situation -- it
20 appears, from what I'm reading,
21 that there was no, at that time,
22 understanding that this included
23 U.S. production, as far as Ms.
24 Wong was concerned.

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1 I don't know. Again, I
2 would be speculating.
3 But the only thing that I
4 can tell you is that if we at Teva
5 corporate had become aware of this
6 situation on June 20th, then the
7 field alert report process would
8 have started at that point.
9 BY MR. STANOCH:
10 Q. Well, you said earlier, too,
11 that supply chain folks were having
12 communications with ZHP about the
13 impurity prior to June 20th, right?
14 A. That is -- that is correct.
15 That is correct.
16 Q. Right. So you know that
17 there was supply chain folks who knew
18 about the impurity with ZHP prior to June
19 28th, right?
20 A. That is correct.
21 Q. And we know from looking at
22 least at Ms. Wong, who is in quality,
23 albeit for a different region, within
24 Teva, was aware of the impurity prior to

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1 June 28th, correct?
2 A. That is correct.
3 MS. LOCKARD: Objection.
4 Form.
5 BY MR. STANOCH:
6 Q. But the field alert was not
7 submitted to the FDA until June 28th?
8 A. As I indicated to you, the
9 field alert was reported to the FDA as
10 soon as I and my organization became
11 aware of the specific details associated
12 with this situation.
13 Q. So different people within
14 Teva were aware of the impurity in the
15 valsartan API for over a week before you
16 were; is that what you're saying?
17 MS. LOCKARD: Objection.
18 Form. Misstates the testimony.
19 THE WITNESS: What I'm aware
20 of is that different people were
21 aware of this situation under a
22 different level of understanding
23 as to what this issue represented.
24 So I'm sure that -- or I

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1 could speculate that if I'm a
2 supply chain organization, they
3 are looking at the issue from a
4 supply chain perspective. Ms.
5 Wong was looking at it from a
6 regional perspective.
7 When the information gets to
8 us, then we look at it from a
9 global perspective. And we are
10 the quality organization, the
11 compliance organization. We have
12 a different level of understanding
13 as to exactly what needs to be
14 done under these circumstances.
15 BY MR. STANOCH:
16 Q. There weren't any procedures
17 in place at Teva to ensure that folks in
18 different functions, such as supply chain
19 or maybe in a -- quality in a different
20 region, passed on urgent information
21 about API impurities to you in your
22 group; is that right?
23 MS. LOCKARD: Objection.
24 Form. Misstates the evidence.

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1 THE WITNESS: The procedures
2 were there. And I'm sure that in
3 different locations, supply chain
4 organization, when they see an
5 issue, they're able to communicate
6 it based on their best
7 understanding.
8 In this situation, I don't
9 know exactly what happened. But
10 they were looking at it from a
11 different perspective.
12 So when you see Ms. Wong,
13 she was actually initiating
14 corrective actions, from a quality
15 perspective, for activities within
16 her region.
17 BY MR. STANOCH:
18 Q. Who is the first person to
19 tell you about the nitrosamine impurity
20 in the valsartan API?
21 A. Oh, I remember this very
22 well. That was -- I was in Italy on that
23 Thursday, and we received a call. I
24 don't remember -- I got it from my vice

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1 president of quality in Europe, Edith
2 Koller-Dette. She communicated the issue
3 to me. I don't recall now exactly who
4 she got the information from.
5 But as soon as we got it,
6 that's exactly the point at which we
7 decided that we needed to file a field
8 alert report.
9 Q. So the first time you heard
10 about the valsartan API contamination
11 issue from ZHP was June 28th?
12 A. That is correct.
13 Q. Can you identify with
14 specificity any procedures at Teva, at
15 the time, that would have covered Ms.
16 Wong or someone in the supply chain or
17 some other function that knew about it
18 earlier to tell you about it sooner than
19 June 28th?
20 A. I would have to look at the
21 procedures. But I'm sure that there are
22 some general procedures that would
23 provide that level of guidance.
24 Q. Sure. Sitting here right

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¹ now, can you recall which procedure, if
² any, would cover that?

A. Potentially the NTM
procedure, notification to management
procedure.

6 Q. Any others?

7 A. I would think that that
8 would be the -- maybe a complaint
9 procedure would be applicable in this
10 case.

11 Q. Okay. Any others?

12 A. It could be -- I'm sure
13 there are others. I just -- I'm thinking
14 about these two at this time.

Q. Was this nitrosamine impurity in the valsartan API from ZHP also an out-of-specification issue?

18 A. When the issue was found,
19 that would fit under the
20 out-of-specification conditions for
21 investigation.

Q. Right. So Teva has policies
concerning the handling of
out-of-specification or out-of-trend

¹ in front of you, sir.

² THE WITNESS: I do.

³ BY MR. STANOCH:

4 Q. And this document appears to
5 be Corporate Policy 0092, entitled,
6 Handling of Out-of-Specification, OOS,
7 and Out-Of-Trend, OOT, Test Results,
8 correct?

⁹ A. That is correct.

Q. And its effective date is
identified as June 8th, 2016?

¹² A. That is correct.

13 Q. And this is the global
14 policy you were referring to earlier,
15 right?

16 A. That is the policy I was
17 referring to, yes.

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¹ issues, correct?

² A. That is correct.

3 Q. And those policies -- sorry.

⁴ Go ahead.

⁵ A. I'm sorry.

6 There is a global policy and
7 then there's local policies and
8 procedures.

9 Q. And the global policy would
10 apply to all Teva sites?

11 A. That is correct.

12 MR. STANOCH: Let's mark the
13 next exhibit, 139.

14

(Whereupon, Exhibit
Teva-139, TEVA-MDL2875-00020376,
Teva CORP-0092, was marked for
identification.)

19 - - -

MR. STANOCH: While you're
pulling that up sir, I'll state
for the record it's Bates ending
20376.

24 Tell me when you have that

■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]

6 A. Allow me to read it for just
7 a second.

8 Q. Sure. Go ahead.

9 Tell me when you're done.

10 A. Yes.

1. **Identify the main topic of the text.**
 2. **Summarize the key points in your own words.**
 3. **Identify the author's purpose and audience.**
 4. **Identify the main topic of the text.**
 5. **Summarize the key points in your own words.**
 6. **Identify the author's purpose and audience.**

[REDACTED]

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1 MS. LOCKARD: Objection.
2 Form.
3 THE WITNESS: Can you repeat
4 the question?
5 BY MR. STANOCH:
6 Q. It was a poor one. I'll
7 repeat it.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 Q. And, again, we know others
16 in Teva, besides you, knew -- were
17 looking at this issue at least as early
18 as June 20th, 2018, if not earlier,
19 correct?
20 A. The only difference here, I
21 think it's important, is the field -- the
22 purpose of the field alert report is,
23 again, to let the agency know about the
24 specific issue with sufficient

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1 information to ensure that the agency has
2 a good understanding of the situation.
3 Between June 28th and July
4 the 3rd, that's the point at which we
5 were able to gather the information that
6 we felt that was necessary to file a
7 field alert report.
8 There is -- it is correct
9 that other people had a certain level of
10 knowledge, but not necessarily the
11 complete understanding of all the
12 information that was needed to file a
13 field alert report prior to this point.
14 Q. Well, the Policy 0092, you
15 know, it states that the investigation
16 does not need to be completed to submit a
17 field alert to the FDA, correct?
18 A. You don't have to have an
19 investigation completed. But, as I
20 indicated to you, you have to have
21 sufficient information to be able to fill
22 out a form that, when received by the
23 FDA, the FDA is able to understand the
24 general concept of what the issue is all

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1 about.
2 Q. Well, Ms. Wong, at least,
3 knew on June 30th that there was an
4 impurity in the valsartan API from ZHP
5 and can create a risk to patient health
6 and safety.
7 You're saying that wasn't
8 enough for you to issue a field alert
9 prior to June 28th?
10 A. What I'm trying to say is
11 that Ms. Wong, at the time when she was
12 looking at the issue from her regional
13 perspective, she did not necessarily
14 understand that this issue involved
15 product that was intended for the U.S.
16 So because of the different
17 markets that are served, I don't know
18 what she was thinking in terms of whether
19 or not she needed to think about, well, I
20 need to report this in a different way.
21 But at the time, more than
22 likely, what Ms. Wong was concerned was
23 with the regional concerns that she had
24 based on the knowledge that she had. She

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1 did not necessarily know that this
2 product may or may not have been
3 distributed in the United States.
4 Q. Well, we can look at her
5 e-mail again. You can pull it up, sir.
6 It's -- again, she knew a
7 few key points, which she highlighted
8 with the Hong Kong regulators. She
9 writes -- she wrote, number one, the
10 impurity, NDMA, is defined as a probable
11 human carcinogen.
12 Do you see that?
13 A. I need to go back to the
14 document, if you don't mind.
15 Q. Sure. Yes, please. Tell me
16 when you're there.
17 A. That would be Number 5?
18 Q. No. That is --
19 A. 138?
20 Q. Correct. Thank you.
21 A. Okay.
22 Q. And Ms. Wong wrote in her
23 original message there, There are a few
24 key points we would like to highlight

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1 here on top of our phone call this
2 morning.
3 Do you see that?
4 A. I'm looking for it.
5 Q. Last page.
6 A. My apologies.
7 Q. Sure. Tell me when you're
8 there.
9 A. You're talking about the
10 July 6th, not the 11:42?
11 Q. Correct.
12 A. Okay. Yep.
13 Q. And she noted that the
14 impurity was NDMA and it's defined as a
15 probable human carcinogen, yes?
16 A. Yes. That's what she
17 indicated, yes.
18 Q. Right. So you're telling me
19 that even though Ms. Wong, at least, and
20 probably others in procurement, knew
21 about a probable human carcinogen in an
22 API, no one was -- within Teva was
23 telling you or your department that
24 something needs to be done about this for

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1 other markets?
2 A. Eventually that
3 communication was told to us. I -- so
4 that is what happened later on in the
5 process. So I -- eventually that
6 happened.
7 Q. Right. It didn't happen
8 until June 28th, correct?
9 A. Correct.
10 Q. Can you tell me why no one
11 else at Teva, procurement, Ms. Wong,
12 anyone else, did not inform you or your
13 department about the valsartan API
14 nitrosamine issue until June 28th?
15 A. That would be a speculation
16 on my part. As I indicated to you
17 before, more than likely they were
18 looking at the issue within the confines
19 of their own responsibilities and their
20 understanding they had of the issue.
21 So as soon as they -- the
22 issue became -- the understanding of the
23 issue became clearer to everybody, that's
24 when, you know, the entire organization

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1 just came together to address the issue
2 in a global way.
3 Q. What Teva region is the Teva
4 Jerusalem facility within?
5 A. That would have been
6 Europe -- there was -- it was its own
7 region. So it was the Asia-Pacific
8 region, if I recall well.
9 Q. That's the same region that
10 Ms. Wong is the associate director for
11 commercial quality, right?
12 A. That is correct.
13 Q. And so a facility in her
14 region is sourcing the same API that
15 she's e-mailing about with Hong Kong from
16 ZHP, and that Jerusalem facility is
17 selling it to the U.S., but still you
18 don't have any information about anyone
19 sharing any notice about this
20 contamination issue until June 28th with
21 you and your department?
22 A. So when you operate within a
23 global organization like this one, and,
24 you know, you talk about commercial

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1 quality, even though there were
2 commercial qualities there, it's a
3 separate entity by itself for which, you
4 know, it has a certain level of
5 responsibility.
6 So I -- again, I would be
7 speculating. But what I see, what she
8 was trying to do, was to address the
9 issues within her region and based on her
10 best understanding of what she needed to
11 do.
12 Q. Are you aware of whether
13 anyone within Teva, prior to June 28th,
14 told anyone at Teva's Jerusalem facility
15 about the ZHP valsartan API nitrosamine
16 contamination issue?
17 A. I am not aware.
18 Q. Are you aware of whether
19 anyone at Teva told anyone at the Malta
20 facility about the ZHP valsartan API
21 contamination issue prior to June 28th?
22 A. When you say "anyone," I
23 couldn't say. It could have been to a
24 supply chain person again. I don't know.

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1 MS. LOCKARD: We've been
2 going -- I'm sorry.
3 We've been going over an
4 hour. So when you get to a good
5 point, can we take a break?
6 MR. STANOCH: Yes, Ms.
7 Lockard. I was done. You did not
8 interrupt. No problem.
9 We can take a break now.
10 That's fine.
11 VIDEO TECHNICIAN: The time
12 is 10:32 a.m. Going off the
13 record.
14 - - -
15 (Whereupon, a brief recess
16 was taken.)
17 - - -
18 VIDEO TECHNICIAN: The time
19 is now 10:49 a.m. Back on the
20 record.
21 BY MR. STANOCH:
22 Q. We're back, Mr. Barreto.
23 Just a yes/no question.
24 Did you speak with your

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1 counsel concerning this deposition during
2 the break?
3 A. Yes.
4 Q. Did you speak with your
5 counsel about this deposition during the
6 last break we took?
7 A. Yes.
8 Q. Okay. So are you familiar
9 with something called an HHA?
10 A. Yes.
11 Q. That's a health hazard
12 assessment?
13 A. That is correct.
14 Q. What's a health hazard
15 assessment at Teva?
16 A. So a health hazard
17 assessment is a medical evaluation that
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 Q. There was a health hazard
2 assessment prepared for the valsartan
3 APIs that Teva was sourcing from ZHP,
4 correct?
5 A. There was one, yes.
6 Q. You recall that process and
7 the preparation of that HHA?
8 A. Yes, I do.
9 Q. You were involved in the
10 preparation of that HHA?
11 A. No, I'm not. That would be
12 a responsibility for the medical
13 organization.
14 Q. Do you recall who in the
15 medical organization prepared the health
16 hazard assessment for the valsartan API
17 that Teva was purchasing from ZHP?
18 A. I'm trying to remember the
19 name of the doctor. At this point, I
20 don't recall. But I can look at it.
21 Q. We'll go through some
22 documents soon.
23 And does the name Siyu Liu
24 sound familiar, L-I-U?

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1 A. Yes, that is correct.
2 Q. First name is S-I-Y-U. Last
3 name, L-I-U.
4 Do you recall that person?
5 A. Yes, I do.
6 Q. And what was that person's
7 role at Teva in July 2018, to your
8 knowledge?
9 A. To my knowledge, he was a
10 medical doctor with responsibility for,
11 again, doing this type of -- the type of
12 assessment that would be required under
13 the HHA guidance.
14 Q. And Teva had a standard
15 operating procedure concerning the
16 preparation of health hazard assessments
17 at the time that Teva became aware of the
18 nitrosamine issue in valsartan API,
19 correct?
20 A. Yes.
21 Q. And that SOP -- I mean, I
22 can put it in front of you, but it --
23 consistent with what you said, it's the
24 medical group, I think you said, who

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1 prepare the health hazard assessment?
2 A. That is correct.
3 Q. Do you recall communications
4 with Raphael Nudelman about the health
5 hazard assessment for the ZHP valsartan
6 API?
7 A. He was a member of the
8 cross-functional team that was working
9 with the valsartan situation. So I'm
10 sure there were communications with him,
11 yes.
12 Q. He's a toxicologist, I
13 think.
14 A. That is -- that is correct.
15 Q. Some of the e-mails I looked
16 at, it looked like he was on vacation
17 when the health hazard assessment was
18 being prepared.
19 Does that ring any bells to
20 you?
21 MS. LOCKARD: Objection to
22 form.
23 THE WITNESS: I don't
24 remember.

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1 BY MR. STANOCH:
2 Q. And who is Eric Drape,
3 D-R-A-P-E?
4 A. So, actually, the spelling
5 of his last name is Drape, because he's
6 French.
7 Q. My apologies. Same
8 spelling, wrong pronunciation. I
9 apologize. Thank you.
10 A. No problem.
11 So Eric Drape was my
12 direct-line supervisor. He was the
13 global head of quality.
14 Q. And how about Tony Delicato?
15 A. So Tony Delicato, he had
16 responsibility for the quality activities
17 with the Americas region.
18 Q. Is that a regulatory role or
19 compliance role or something else, to
20 your knowledge?
21 A. It's mostly a quality role.
22 But, obviously, there are compliance
23 activities that fall within that
24 responsibility.

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1 Q. And do you recall the level
2 of recall -- well, strike that.
3 Teva issued a recall
4 concerning its finished-dose valsartan
5 products that contain ZHP valsartan API,
6 correct?
7 A. That is correct.
8 Q. And that was for all Teva
9 valsartan finished dose on the market at
10 the time that had ZHP valsartan API in
11 it, correct?
12 A. That is correct.
13 Q. And my understanding is
14 there is multiple classifications of a
15 recall level; is that right?
16 A. That is correct.
17 Q. Do you recall the level of
18 recall that Teva instituted for the
19 valsartan finished-dose products that it
20 sold in the United States that contained
21 ZHP's valsartan API?
22 A. If I'm not mistaken, that
23 would have been a Class I recall.
24 Q. And would that be the

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1 highest class recall under Teva's
2 procedures?
3 A. It's the highest recall
4 level under Teva and FDA's procedures.
5 MR. STANOCH: I'm going to
6 mark the next exhibit, sir. Stand
7 by.
8 I'm marking Teva
9 Exhibit-140, which is Bates
10 beginning 934333.
11 - - -
12 (Whereupon, Exhibit
13 Teva-140,
14 TEVA-MDL2875-0934333-4435, 7/5/18
15 E-mail, Sawyer to Barak, was
16 marked for identification.)
17 - - -
18 BY MR. STANOCH:
19 Q. Sir, take a moment to look
20 at that. And let me know when you have
21 it.
22 A. I do have it.
23 Q. This appears to be an e-mail
24 chain, with the topmost message from Mr.

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1 Corey Sawyer, dated July 5th, 2018, to
2 various individuals, including yourself,
3 at Teva.
4 Do you see that?
5 A. Yes, I do.
6 Q. And it's regarding the
7 valsartan HHA July 2018 NDMA draft?
8 A. Okay. Yes.
9 Q. So this e-mail chain is
10 about the preparation of the health
11 hazard assessment that we had just been
12 talking about that Teva prepared
13 concerning the ZHP valsartan API, right?
14 A. Yes.
15 Q. And if you'd look at the
16 message on the second page from Mr.
17 Delicato on July 25th, 2018.
18 A. Yes.
19 Q. And he has some comments to
20 Dr. Liu, who it looks like he had been
21 preparing the draft, and then he also has
22 a summary of the recall classifications
23 there in his e-mail.
24 Do you see that?

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1 A. Yeah, I see that.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 Q. And that is consistent with
13 Teva's procedures defining the level of
14 recalls, correct?
15 A. That would be the case, yes.
16 Q. And, again, Teva instituted
17 a Class I recall for its valsartan
18 finished-dose products in the United
19 States that included ZHP valsartan API,
20 right?
21 A. That is correct.
22 Q. And Mr. Delicato writes in
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

Page 157

[REDACTED]

8 And there's a reason for
9 that. The information that we had at the
10 time did not make any sort of link of the
11 presence of the nitrosamines to any
12 human-related, you know, cancer or any
13 other type of link, from a carcinogenic
14 perspective.
15 So to make those statements
16 as indicating that may increase the risk
17 of cancer in a few patients, that --
18 there was no literature, there was no
19 data that we were aware of. So from our
20 perspective, we felt it was important to
21 clarify this statement from Dr. Liu,
22 because in the absence of data -- the
23 statement, without data, could be
24 interpreted in different ways, and we

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1 wouldn't have the data to support the
2 claim that it may increase the risk of
3 cancer in a few patients. We just didn't
4 have that information.
5 So from my perspective, we
6 felt that, you know, we needed to sort of
7 put this in a context that was
8 reasonable.
9 Q. The question was, do you
10 remember that being your recommendation,
11 right?
12 And the answer is yes to
13 that?
14 A. It is yes. But I felt that
15 it was important to provide
16 clarification.
17 Q. Sure. Sure.
18 And you're not a medical
19 doctor, right?
20 A. I am not a medical doctor.
21 Q. You're not a toxicologist,
22 are you?
23 A. I'm not a toxicologist.
24 Q. You don't hold yourself out

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1 as an expert in pharmacovigilance, do
2 you?
3 A. I do not hold myself as an
4 expert in pharmacovigilance, no.
5 Q. You don't have any training
6 in epidemiology, biostatistics, anything
7 like that, do you?
8 A. No.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 We also felt the need to, as
24 part of the assessment that we were
doing, to understand that the elements

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1 included were supported. So while it is
2 correct that I don't have all those
3 specialties, I do have the experience to
4 evaluate these records and make
5 recommendations on them.
6 Q. Right. And the conclusion
7 was not Dr. Liu's conclusion. He ended
8 up adopting the recommended conclusion
9 you said, correct?
10 A. I think he ended up making
11 the recommendation that he understood
12 would fit the expectations of the data
13 that we were asking him to support his
14 recommendation with. The data was not
15 there.
16 Q. You recommended the
17 conclusion, and that's ultimately the
18 conclusion that ended up in the health
19 hazard assessment, yes?
20 A. But -- yes. But that is the
21 HHA assessment, not mine.
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 And so we were adopting
8 language that we saw was being used by
9 the regulatory authorities in this case.
10 Q. Did you do any analysis
11 yourself to quantify how many patients
12 may develop cancer from any use of
13 valsartan containing ZHP's valsartan API?
14 A. There was -- there was no
15 analysis on our part. What we wanted to
16 convey to the agency was what we had
17 received as input from other regulatory
18 authorities.
19 Q. So what did -- how many --
20 quantify it.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 So, again, I would leave
7 that discussion of whether or not a study
8 was conducted to toxicologists. But the
9 information we had at the moment was that
10 there was potential long-term use of the
11 product, based on the input from the
12 regulators.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MS. LOCKARD: Object to
10 form. Asked and answered.
11 THE WITNESS: No.
12 BY MR. STANOCH:
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. Do you remember specifically
23 talking to him about that or are you
24 guessing?

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1 A. I don't remember. But he
2 copied me on that, so that was clear to
3 me.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 A. Can you repeat the question?
2 MR. STANOCH: Madam
3 Reporter, if you would not mind.
4 - - -
5 (Whereupon, the court
6 reporter read the following part
7 of the record:
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 Q. In the preparation of the
5 health hazard assessment, did you come to
6 have an understanding of whether NDMA was
7 a carcinogen?
8 A. The understanding we had was
9 that it was a potential carcinogen, yes.
10 Q. Well, not just a potential
11 carcinogen, isn't it correct that NDMA is
12 a potent mutagenic carcinogen?
13 MS. LOCKARD: Objection.
14 Form. Vague.
15 THE WITNESS: The
16 understanding that we have is that
17 the studies that have been
18 conducted have been in animals,
19 and the correlation between these
20 findings and nitrosamines having a
21 carcinogenic impact in humans,
22 that has not been established.
23 That's why we were concerned.
24 BY MR. STANOCH:

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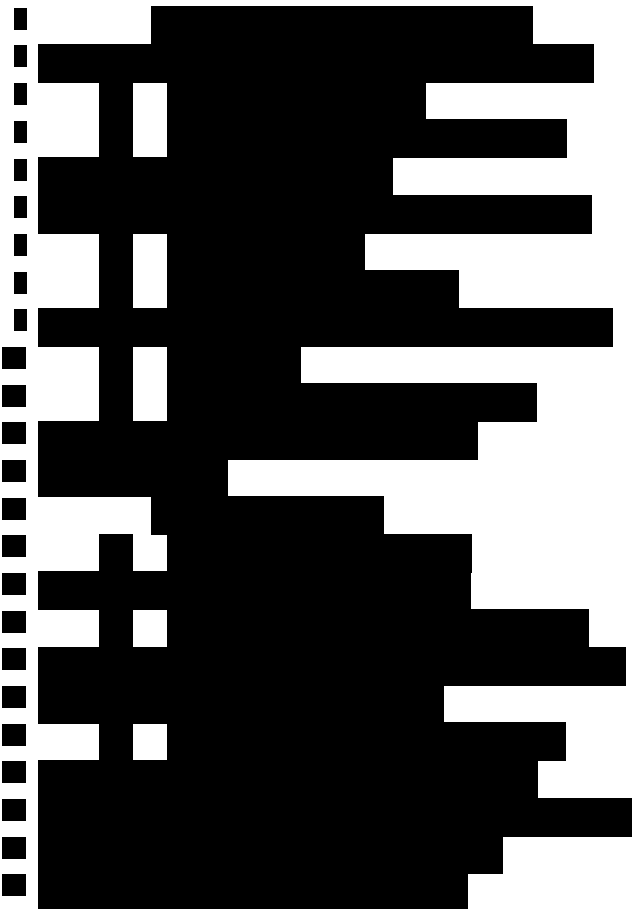
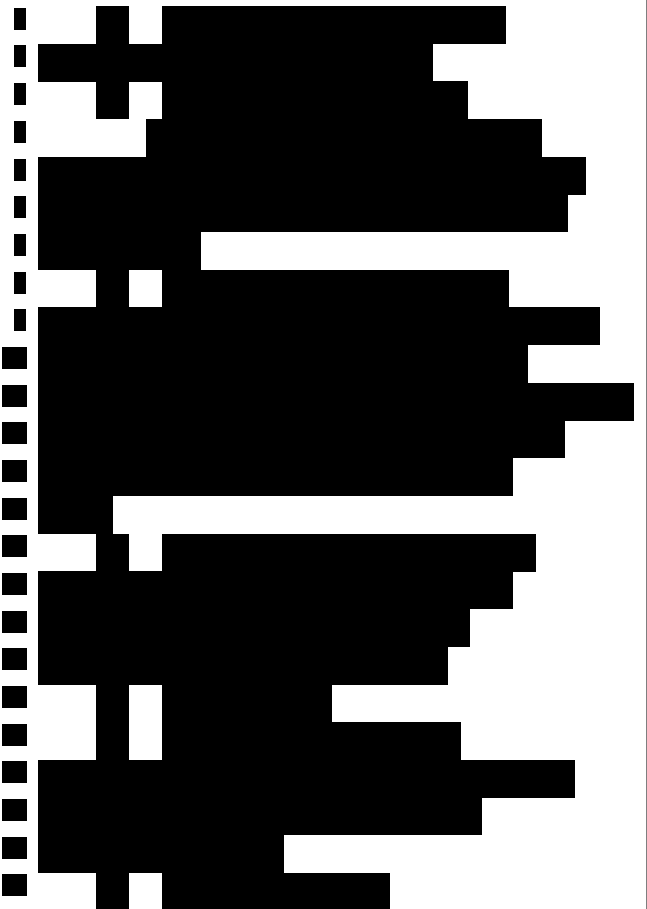
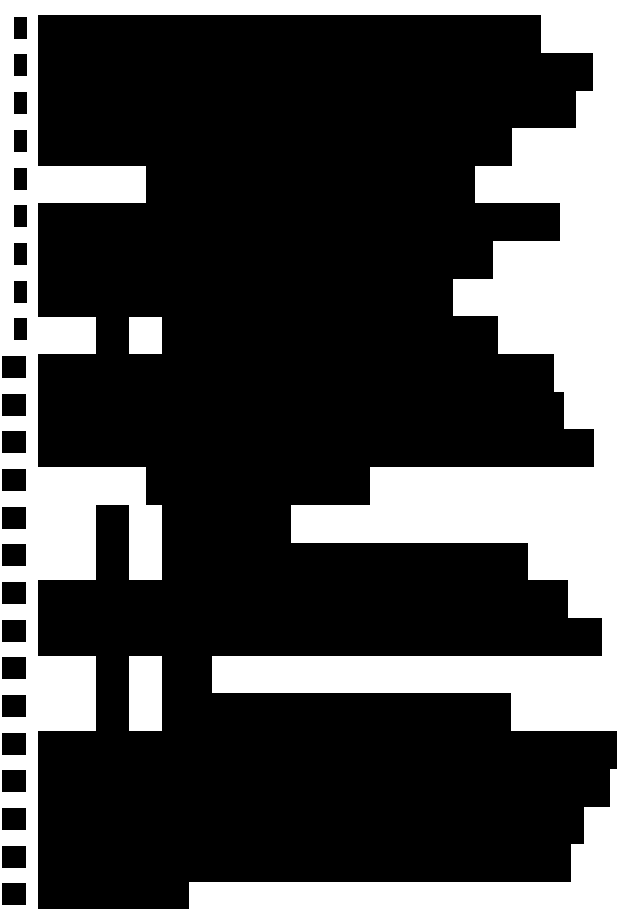
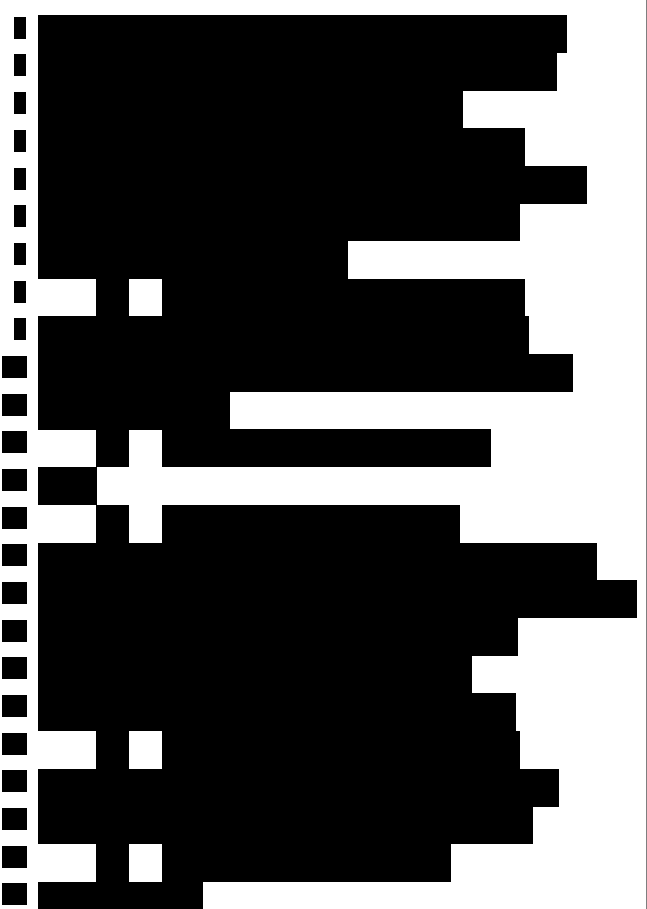
1 Q. So you don't agree that NDMA
2 is a potent mutagenic carcinogen?
3 A. I agree that it's a potent
4 carcinogenic impurity.
5 What I am saying is that we
6 have to make a distinction, where is it
7 that it is carcinogenic?
8 MR. STANOCH: I'll mark
9 Teva-141.
10 - - -
11 (Whereupon, Exhibit
12 Teva-141,
13 TEVA-MDL2875-00020519-0525, 7/4/18
14 E-mail, Barreto to Drape, was
15 marked for identification.)
16 - - -
17 BY MR. STANOCH:
18 Q. Tell me when you have that,
19 sir.
20 MR. STANOCH: While you're
21 doing that, for the record, I'll
22 state it's Bates ending 20519.
23 THE WITNESS: Yes, I have
24 it.

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1 BY MR. STANOCH:
2 Q. This appears to be an e-mail
3 chain, topmost message from you to Eric
4 Drape, July 4th, 2018; is that right?
5 A. Yes.
6 Q. Do you recall this e-mail
7 chain?
8 A. Yes.
9 MS. LOCKARD: I'm sorry.
10 Okay. Sorry to interrupt. I
11 misheard the date.
12 THE WITNESS: You're
13 speaking about the 7:39 a.m. page?
14 BY MR. STANOCH:
15 Q. I was looking at the topmost
16 message from you to Mr. Drape.
17 A. Yes.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. Okay. We're on the same
23 page, then.
24 So if you could turn, then,

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1 to the next page, the message from Mr.
2 Nudelman?
3 A. Yes.
4 Q. And, again, Mr. Nudelman was
5 a toxicologist at Teva, right?
6 A. That is correct.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 A. I'm going there, sorry.
14 I'm looking for it. Is that
15 from Mr. Nudelman to Mr. Drape?
16 Q. It's from Mr. Nudelman to,
17 it looks like, Corey Sawyer and Siyu Liu.
18 A. It says, My apologies for
19 interrupting -- nope.
20 Q. No. Go one, two, three
21 messages up in the chain.
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

<p>Page 170</p> 	<p>Page 172</p> 
<p>Page 171</p> 	<p>Page 173</p> 

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1 the compliance of what we call the CAC,
2 the corporate action committee. This was
3 processed within that organization.
4 We were working also with
5 the supply chain organization, because
6 they are the ones who have consistent and
7 direct contact with the suppliers.
8 So we indicated to each and
9 every supplier that we needed to have
10 that certification.
11 Q. So who on this
12 cross-functional team was responsible for
13 communicating with each valsartan API
14 supplier?
15 A. So, again, supply chain
16 personnel from different regions. And
17 Corey Sawyer, who worked for me and
18 Claire Lyons.
19 Q. Who in the supply chain
20 department was contacting various API
21 suppliers?
22 A. Our main contact was Jens.
23 I'm trying to remember now his last name.
24 Q. Nassall?

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1 A. Nassall, yes.
2 Q. Was he the main contact with
3 all the other API suppliers of valsartan
4 API to Teva, or was there someone else?
5 A. No, he was not. There were
6 different supply chain personnel in
7 different regions.
8 So if I recall, you know,
9 there was one person in Spain speaking
10 with suppliers from Spain. So it was --
11 it was -- again, it was a team effort.
12 Q. Who do you recall was the
13 person primarily responsible for
14 communicating with the manufacturer
15 Jubilant about valsartan API?
16 A. I don't recall who was that
17 person. It could have been Jens Nassal.
18 Q. How about the person who was
19 primarily responsible for communicating
20 with Mylan?
21 A. Again, I'm speculating, it
22 could have been Jens Nassal.
23 Q. And who was having the
24 primary contact with ZHP at this time in

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1 early July 2018?
2 A. I think it was Jens Nassall
3 as well. But, again, I'm speculating at
4 this point.
5 MR. STANOCH: I'm going to
6 mark the next exhibit, sir,
7 Teva-143, Bates ending 20744.
8 - - -
9 (Whereupon, Exhibit
10 Teva-143, TEVA-MDL2875-00020744,
11 7/5/18 E-mail, Barreto to
12 Koller-Dette, was marked for
13 identification.)
14 - - -
15 BY MR. STANOCH:
16 Q. Tell me when you've been
17 able to pull it up.
18 A. Got it.
19 Q. And this appears to be an
20 e-mail chain, topmost message is from
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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1 system or -- in place at Teva at the time
2 that would have let you or someone else
3 find out all the product holds in place?
4 A. There is potential for that
5 central system to be in place. I
6 couldn't speak to it at this point.
7 Q. Right. I'm only asking
8 because you said you would have to
9 contact someone at a distribution center.
10 And Teva has a number of
11 distribution centers, I imagine, yes?
12 A. That is correct. Or, as I
13 did in the past, I would just speak with
14 the global supply chain vice president,
15 and he still would go to the distribution
16 centers and ask for that information.
17 Q. Would a product hold only
18 relate to the finished product?
19 A. A product hold could relate
20 to both finished product and API. It
21 could relate to excipients. It depends
22 on what is it that we need to put on
23 hold.
24 Q. Do you recall whether or not

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[REDACTED]

7 Q. Well, you were a senior
8 quality executive at the time in July
9 2018.
10 How would you know whether
11 or not a hold was in place for a
12 particular product or not?
13 A. I would ask for that
14 information. And then I would obtain it
15 through, you know, whatever distribution
16 center was responsible for providing that
17 response.
18 So I don't have access to --
19 I didn't have access to each distribution
20 center database. But I could -- I could
21 send a request -- an e-mail and request a
22 certification that something was placed
23 on hold.
24 Q. So there was no central

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1 Teva ever had a hold placed on all
2 finished-product valsartan in early July
3 of 2018?
4 A. As I indicated to you, I'm
5 trying to recall, there may have been,
6 like, a one-day or two-day hold based on
7 the initial information, acting on, let's
8 say, a conservative approach.
9 I don't recall now. But
10 that's probably what could have happened.
11 Q. How about holds for API? Is
12 there a different system for that?
13 A. No, it's the same system.
14 It's just a product code that is assigned
15 to the API.
16 So I'm sure that every
17 valsartan lot from ZHP was placed on
18 hold. The same -- the same for the
19 manufacturing process, we also put a hold
20 on that.
21 Q. So you recall Teva putting a
22 hold on all valsartan API from ZHP as
23 well as the manufacturing of that API
24 into a finished-dose product?

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1 A. That is correct.
2 Q. Do you recall whether Teva
3 ever had a hold on all valsartan API,
4 regardless of supplier, in place?
5 A. As I indicated to you, if
6 there was a hold, and I'm trying to
7 remember now, it would have been -- it
8 would have been a temporary hold while,
9 you know, we were trying to understand
10 the implications from this situation.
11 Q. And sitting here today, you
12 can't remember whether there would be a
13 centralized system that you, as quality,
14 could access to see which API or finished
15 product was subject to a hold?
16 MS. LOCKARD: Objection.
17 Asked and answered.
18 THE WITNESS: As I said, I
19 am not sure whether or not there's
20 such a central system.
21 But if we wanted to know
22 what is on hold in the entire
23 global network, this is something
24 that can be done.

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1 BY MR. STANOCH:
2 Q. And who would you ask to
3 find that out?
4 A. I would speak with the vice
5 president of supply chain.
6 Q. And who was that at the time
7 in July of 2018?
8 A. That would have been Daniel
9 Hoey.
10 Q. Could you spell the last
11 name?
12 A. H-O-E-Y.
13 Q. Thank you.
14 And would that be for holds
15 on finished product as well as API or
16 just one or the other?
17 A. For everything.
18 Q. Do you ever recall speaking
19 to Mr. Hoey, or anyone in his department,
20 about holds on valsartan finished product
21 or valsartan API in July of 2018?
22 A. More than likely there was a
23 discussion, as I said, yes.
24 Q. Can you recall specifically

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1 any discussion you had with him?
2 A. I'm sure that there was a
3 discussion around the hold for valsartan
4 from ZHP because we needed to ensure that
5 that product was not distributed.
[REDACTED]

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1 Q. You mentioned product codes
2 earlier.
3 Would the product codes
4 trigger what would be put on hold
5 globally?
6 A. So every item that is
7 received is given a product code. So the
8 global notification actually comes from
9 the corporate organization, where we send
10 that notification, through the GMP
11 process, to the sites where we say, put
12 product on hold.
13 Q. To your knowledge, is the
14 code for valsartan API from a given
15 supplier the same throughout the global
16 Teva network?
17 A. I don't know the answer to
18 that question.
[REDACTED]

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1 A. Let me read here.
2 Q. Sure.
3 A. You're talking about the
4 last document that we've been discussing,
5 right?
6 Q. Yes. The e-mail.
7 I'm looking at the part in
8 bold and italics that you wrote.
9 Do you see that?
10 A. Oh, I see what you're
11 saying.
12 Correct.

[REDACTED]

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[REDACTED]

Page 192

[REDACTED]

Page 193

[REDACTED]

5 BY MR. STANOCH:
6 Q. Well, it's Teva's obligation
7 to ensure its products are safe and
8 efficacious, right?
9 A. Our obligation is that our
10 products are safe, efficacious -- you
11 know, safety, efficacy, quality and
12 purity of the products, yes.
13 Q. Teva didn't need FDA's
14 permission to put a hold on other API
15 suppliers' valsartan API, did it?
16 A. We didn't need permission
17 from the FDA. But we needed data to
18 ensure that there was scientific
19 rationale for putting product on hold.
20 Otherwise, we would create a drug
21 shortage situation which would create a
22 different set of challenges and problems
23 for us, our patients and the regulators.
24 Q. Teva kept buying valsartan

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1 API from Mylan, even though it knew at
2 the time that ZHP had a nitrosamine issue
3 in its API, right?
4 A. Can you repeat the question?
5 Q. Teva was still purchasing
6 valsartan API from Mylan at the same time
7 it was putting a hold on ZHP valsartan
8 API?
9 A. That is correct. And --
10 Q. And -- sorry.
11 A. I just want to say, I mean,
12 this is a very evolving process. This is
13 a process that is going -- you know,
14 changing from a -- day to day.
15 So even in the case where
16 you mentioned Mylan, Swissmedic had
17 tested product from Mylan and had
18 indicated to us that they had not seen
19 any nitrosamines in their testing.
20 So there's a lot of
21 information that is being shared. So our
22 decision-making process is not only based
23 on the ZHP information but it's also
24 based, as the situation evolved, on input

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1 that we're getting from regulators.
2 Q. Nothing in this e-mail we're
3 looking at mentions any communication
4 from Swissmedic, does it?
5 A. This is -- this is what
6 happens later on in the process. So
7 Swissmedic picks up on this, you know,
8 process later on.
9 So no. But at the time,
10 based on our knowledge, the only problem
11 that we had identified was associated
12 with valsartan from ZHP. We had no
13 information about any other API supplier.
14 So as far as we knew,
15 putting product on hold without
16 information was not the right thing to
17 do.
18 Q. First of all, you just said,
19 right, communications with Swissmedic
20 happened later on, not in early July
21 2018, right?
22 A. Correct.
23 Q. And then, second, Teva was
24 saying nobody else contacted it about a

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1 similar problem, but Teva hadn't done
2 anything, by that point in time, to reach
3 out affirmatively and say, hey, Mylan,
4 tell us how your valsartan API is with
5 respect to nitrosamines; had that
6 happened yet?
7 A. As far -- not at that point.
8 But this is part of the
9 evolution of the process where we put
10 together a certification process where we
11 are asking our API suppliers to give us
12 sufficient technical information for us
13 to be comfortable that they did not have
14 issues. So we proactively actually
15 reached out to the API suppliers.
16 Q. So instead of just putting a
17 hold on valsartan API from any supplier,
18 Teva just kept buying, processing and
19 selling finished dose with Mylan API,
20 with Jubilant API, et cetera, without
21 having received any information from
22 those suppliers or doing any analysis on
23 Teva's own?
24 MS. LOCKARD: Objection to

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1 the form of the question.
2 THE WITNESS: The testing of
3 those products that we received
4 indicated -- from these suppliers
5 indicated that those suppliers
6 were fulfilling the specifications
7 established.
8 At that point, we're still
9 trying to understand the next
10 steps that we're going to take.
11 And from a proactive perspective,
12 we have product meeting the
13 specifications, but we still,
14 later on, take the proactive
15 approach to seek certification
16 from the API suppliers.
17 BY MR. STANOCH:
18 Q. NDMA was not in the
19 specification for any valsartan API from
20 anyone, correct?
21 A. That is correct.
22 Q. And, in fact, no
23 nitrosamines was in the specification for
24 any API suppliers' API that Teva was

<p>Page 198</p> <p>1 buying, correct?</p> <p>2 A. That is correct.</p> <p>3 Q. So specification testing,</p> <p>4 whatever extent it was being done, might</p> <p>5 not necessarily be enough to know whether</p> <p>6 there was nitrosamines in these other</p> <p>7 suppliers' valsartan API, correct?</p> <p>8 A. But I think it's</p> <p>9 important -- I think -- I'd like to</p> <p>10 provide some clarification.</p> <p>11 When you look at the</p> <p>12 manufacturing process for ZHP, that</p> <p>13 process was different from the</p> <p>14 manufacturing process that we had at</p> <p>15 Mylan. So the fact that you have a</p> <p>16 problem at one supplier site does not</p> <p>17 necessarily imply that you have the same</p> <p>18 problem at another location.</p> <p>19 So with the knowledge that</p> <p>20 we had at the time, we felt that the most</p> <p>21 important thing to do was to continue the</p> <p>22 investigation with the -- ZHP's</p> <p>23 situation. We were proactively seeking</p> <p>24 more information from our suppliers.</p> <p>Page 199</p> <p>1 And as information became</p> <p>2 available and things change, then we took</p> <p>3 the necessary proactive actions, whether</p> <p>4 it was a recall, additional holds.</p> <p>5 So the hold, from my</p> <p>6 perspective, counsel, the holds happened</p> <p>7 at the time we -- the data indicated that</p> <p>8 we needed to -- to take -- to put those</p> <p>9 holds in place.</p> <p>10 Q. So you're saying in early</p> <p>11 July 2018, Teva wanted to do more</p> <p>12 analysis of other valsartan API</p> <p>13 suppliers' product to evaluate whether</p> <p>14 the nitrosamine impurity might be in it?</p> <p>15 A. Yes.</p> <p>16 Q. And that would include</p> <p>17 understanding the solvents used?</p> <p>18 A. At the time when we are</p> <p>19 working with the ZHP situation, there was</p> <p>20 no discussion about solvents. The issue</p> <p>21 about solvents came later on when we</p> <p>22 gained knowledge of the situation with</p> <p>23 Mylan.</p> <p>24 So the discussion that we</p>	<p>Page 200</p> <p>1 had regarding ZHP was around the fact</p> <p>2 that the manufacturing process had</p> <p>3 changed and then there were certain</p> <p>4 conditions within the manufacturing</p> <p>5 process that would trigger this type of</p> <p>6 formation of this impurity.</p> <p>7 There was no knowledge about</p> <p>8 anything else other than what we had at</p> <p>9 the moment. As the situation evolved,</p> <p>10 that's when we tackled each issue in a</p> <p>11 certain way independently, because each</p> <p>12 issue was different, to a certain extent.</p> <p>13 Q. Well, part of the issue, as</p> <p>14 you understood it, concerning ZHP was a</p> <p>15 process issue involving the degradation</p> <p>16 of the solvent dimethylamine, correct?</p> <p>17 A. So to explain. The issue</p> <p>18 with the ZHP, it's what I would call a</p> <p>19 form of secondary issue, because you have</p> <p>20 the -- you have the Tetrasol grade</p> <p>21 formation through this -- using DMS --</p> <p>22 the DMS actually generates low traces of</p> <p>23 dimethylamine. And then those low traces</p> <p>24 of dimethylamine, when they come in</p> <p>Page 201</p> <p>1 contact, later on in the next step, with</p> <p>2 nitrous acid, that's when these</p> <p>3 formations of the impurities happens.</p> <p>4 So it's like a secondary</p> <p>5 issue, because it's not exactly directly</p> <p>6 related to the main ingredients reacting</p> <p>7 with each other. It's a by-product that</p> <p>8 is caused by traces of small degradants</p> <p>9 that are generated in the process.</p> <p>10 Q. You agree that the</p> <p>11 nitrosamine contamination in the</p> <p>12 valsartan API, it's a process impurity,</p> <p>13 not a degradation impurity, right?</p> <p>14 A. What I'm saying is that to</p> <p>15 the extent that it's a process impurity,</p> <p>16 it happens in the process but at the</p> <p>17 stage where, when you are assessing the</p> <p>18 manufacturing process, those small traces</p> <p>19 of degradants coming from the DMS turning</p> <p>20 into DEA, those you would not necessarily</p> <p>21 be in a good position to predict, and</p> <p>22 that's what I was saying.</p> <p>23 Q. The question was merely,</p> <p>24 sir, do you agree that nitrosamine</p>
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1 contamination of valsartan API, it's a
2 process impurity, not a degradation
3 impurity, correct?
4 A. That is correct.
5 Q. Right. And that means that
6 the concentration of the impurity in the
7 API carries over to the finished product,
8 right?
9 A. Yes.
10 Q. Because the impurity is not
11 arising when the finished product is
12 degrading in some way, right?
13 A. It comes with the API, as
14 far as we know.
15 Q. And then earlier you were
16 talking about it is important to know
17 what happens in the process.
18 So a part of that is an
19 analysis of the route of synthesis for
20 creating the valsartan API, isn't it?
21 A. Correct.
22 Q. And you would think that
23 Teva would have looked at the route of
24 synthesis for the other valsartan APIs it

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1 was purchasing besides ZHP's, right?
2 A. What we wanted to do -- the
3 route of synthesis is pretty much an
4 intellectual property for the company,
5 and most companies do not want to share
6 the route of synthesis.
7 So what we did is we asked
8 the API suppliers to perform a route of
9 synthesis analysis, to have that route of
10 synthesis analysis documented and sent to
11 us.
12 And then internally, with
13 our experts, those routes of synthesis
14 analysis assessments were again evaluated
15 internally by Teva personnel.
16 Q. At the time of July 5th,
17 2018, Teva didn't have the route of
18 synthesis for its valsartan API
19 suppliers, did it?
20 A. We would not have the route
21 of synthesis from any API supplier. We
22 would have access to manufacturing
23 records.
24 But the extent to which an

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1 API supplier would share a route of
2 synthesis, that's just something that
3 would not necessarily be possible.
4 Q. Right. It would be very
5 helpful to Teva's analysis to have the
6 full route of synthesis so Teva can
7 conduct its own evaluation of the
8 valsartan API; is that fair?
9 A. Under ideal conditions, yes.
10 But that's not the way the industry
11 works.
12 Q. Did Teva ask non-ZHP
13 suppliers of valsartan API for routes of
14 synthesis?
15 A. As I indicated to you, we
16 asked for a route of synthesis analysis
17 from them. If some API suppliers, I'm
18 trying to remember, gave us sections of
19 their route of synthesis, that's
20 possible. I remember certain -- but you
21 would not get the full route of
22 synthesis.
23 MR. STANOCH: I'm going to
24 mark the next exhibit, Teva-144.

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1 - - -
2 (Whereupon, Exhibit
3 Teva-144,
4 TEVA-MDL2875-00057196-7197, 7/6/18
5 E-mail, Sawyer to Drape, was
6 marked for identification.)
7 - - -
8 THE WITNESS: Okay.
9 MR. STANOCH: It's Bates
10 ending 57196.
11 BY MR. STANOCH:
12 Q. Tell me when you have it,
13 sir.
14 A. Yes.
15 Q. This is an e-mail chain,
16 topmost message is from Corey Sawyer,
17 dated July 6th, 2018, to Mr. Drape and
18 yourself, copying others.
19 Do you see that?
20 A. Yes, I do.
21 Q. And the attachment is for
22 Valsartan synthesis routes of Mylan and
23 Jubilant, right?
24 A. Yes.

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1 Q. And at this time, Teva was
2 purchasing valsartan API from Mylan and
3 Jubilant as well as ZHP, right?
4 A. Yes.
5 Q. And Mr. Sawyer was writing
6 to you and others about Teva's analysis
7 of the processing of the valsartan API by
8 Jubilant and Mylan, right?
9 A. Yes.
10 Q. And with respect to Mylan,
11 Mr. Sawyer has an excerpt from another
12 Teva person named Katherine, right, that
13 says, The document attached is a copy of
14 CEP from which we can see only the
15 solvent analyzed at final stage.
16 According to this, Mylan is not using
17 DMF, hence possibility is negligible.
18 They have not provided ROS document,
19 hence actual evaluation could not be
20 done.
21 Did I read that right?
22 A. My apologies. You're
23 reading from the top?
24 Q. I'm looking at the first --

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1 the topmost e-mail message that begins,
2 To Mylan, in bold.
3 Do you see it?
4 MS. LOCKARD: You can read
5 as much of the document as you
6 need to, though.
7 THE WITNESS: Okay.
8 I'm reading here. I'm
9 trying to see where you're reading
10 from. Are you reading from the
11 top e-mail, 2:49 p.m.?
12 BY MR. STANOCH:
13 Q. 3:02:49, correct, sir?
14 A. 3:02.
15 Yes. And what is your
16 question? Sorry.
17 Q. My question was just did I
18 read the excerpt correctly, where it
19 says, To Mylan, the document attached is
20 a copy of CEP from which we can see only
21 the solvent analyzed at final stage.
22 According to this, Mylan is not using
23 DMF, hence possibility is negligible.
24 They have not provided ROS document,

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1 hence actual evaluation could not be
2 done.
3 Do you see that?
4 A. Yes, I see that.
5 Q. So this is reflecting that
6 because Mylan had not provided the full
7 route of synthesis document, Teva
8 couldn't do an actual evaluation to
9 determine the extent to which Mylan's
10 valsartan API could have nitrosamine
11 contamination, right?
12 A. And this goes to what I was
13 just telling you before, that the -- most
14 companies will not -- most companies will
15 not share the route of synthesis
16 analysis -- sorry, the route of
17 synthesis.
18 So this is one where the
19 certification that they provided said, we
20 don't use DMF.
21 Q. Was -- go ahead. I don't
22 want to cut you off, sir. You're the
23 witness.
24 A. Because we know DMF is

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1 important in the process of nitrosamine
2 formations.
3 Q. It looks like Jubilant had
4 provided their route of synthesis, right?
5 A. Let me read.
6 They may have or may not. I
7 don't know.
8 Q. And, again, the very first
9 e-mail in this is from Eric Drape. And
10 he mentioned, in part, that, I discussed
11 with Carlo, and we are of the opinion
12 that we can lift the hold on batches from
13 other suppliers if exempt of Huahai
14 intermediates.
15 Do you see that?
16 A. Correct.
17 Q. Does that refresh your
18 recollection that there was a hold on all
19 valsartan API but then it was lifted as
20 to non-ZHP valsartan API?
21 A. And that's exactly what I
22 told you before, that there could have
23 been, and there was, an immediate and
24 temporary hold while we understood

<p>Page 210</p> <p>1 whether or not this was an issue that was 2 isolated to one supplier or all 3 suppliers, all -- you know, all valsartan 4 products. That's what I said. 5 Q. Sure. But then it looks 6 like Teva was lifting the hold as to 7 Mylan valsartan API, even though it could 8 not conduct the actual evaluation because 9 they didn't get enough documentation from 10 Mylan. 11 That's what it says here in 12 the top e-mail, isn't it? 13 A. No, no. What it says is 14 that when the ZHP situation came up, we 15 active -- proactively put every valsartan 16 that was produced on hold, regardless of 17 supplier. 18 And then we discussed, from 19 a risk-based approach, whether or not 20 there was a reason to maintain that hold 21 on a more long-term basis. And we 22 decided that there was no reason because 23 there was no data at the point that would 24 justify keeping product on hold.</p> <p>Page 211</p> <p>1 Q. Teva lifted its hold on 2 Mylan valsartan API -- or product 3 containing Mylan valsartan API without 4 actually conducting an evaluation of the 5 Mylan route of synthesis; isn't that 6 right? 7 A. Because that process came 8 later on in the -- in the whole chain of 9 events that we followed. So at the time, 10 that decision to seek for -- a route of 11 synthesis evaluation, that was not 12 precedent at the time. 13 That came as we decided, 14 later on, to continue to ask for more 15 information. 16 Q. Well, this isn't later on, 17 sir, this is July 6th, 2018, isn't it? 18 A. This is -- but this is about 19 ZHP. So at that point, the only 20 information that we have is ZHP is the 21 problem. We don't have any reason to 22 believe that there are other products 23 involved. 24 Q. At the time you didn't have</p>	<p>Page 212</p> <p>1 any reason to believe there was not a 2 problem either, though, with the Mylan 3 valsartan API, did you? 4 A. At the time we -- what we 5 knew was that the product was fulfilling 6 specifications and that in light of the 7 fact that we had not received any 8 notification from other suppliers, the 9 approach to take was to continue with the 10 manufacturing process to ensure that 11 patients had access to the medication. 12 Q. ZHP's valsartan API was 13 fulfilling the specifications, too, 14 wasn't it? 15 MS. LOCKARD: Object to 16 form. Asked and answered. 17 THE WITNESS: And for the 18 ZHP situation, based on the 19 additional information, regardless 20 of them meeting specifications, we 21 identified that there was an 22 issue. That's the difference. 23 BY MR. STANOCH: 24 Q. Right. My only point, sir,</p> <p>Page 213</p> <p>1 for everyone listening to this, is that 2 just because a given supplier's valsartan 3 API was fulfilling specifications did not 4 mean it was free of nitrosamine 5 contamination and should be distributed, 6 correct? 7 MS. LOCKARD: Object to 8 form. Asked and answered. 9 Argumentative. 10 THE WITNESS: At the time 11 when we made the decision to 12 continue to manufacture, we had no 13 information whatsoever that would 14 indicate that we had a problem or 15 an issue with any of the products 16 manufactured by other suppliers. 17 That is -- that is normal. 18 BY MR. STANOCH: 19 Q. Teva lifted its hold of 20 product with Mylan valsartan API without 21 any evaluation of the Mylan route of 22 synthesis, correct? 23 A. At the time when we made 24 that lift, we did not see a need to do</p>
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<p>Page 214</p> <p>1 that route of synthesis evaluation. 2 Q. Teva lifted the hold on 3 Mylan valsartan API, and products 4 containing the same, without doing any 5 testing for nitrosamines in the Mylan 6 valsartan API or the finished product 7 containing same? 8 A. At the time, the information 9 we had was that these products were 10 fulfilling specifications. We did not 11 have any testing, analytical methods for 12 nitrosamines, let's say, to look into 13 those products. We did not have the 14 equipment to do that either. 15 So that is something that as 16 more information became available, we put 17 in place a strategy to ensure that we 18 would have those capabilities. 19 Q. Teva lifted the hold on the 20 Mylan valsartan API, and any product 21 containing same, without doing any 22 testing for nitrosamines in it, correct? 23 MS. LOCKARD: Objection. 24 Asked and answered.</p> <p>Page 215</p> <p>1 MR. STANOCH: You can 2 answer. 3 Sir, you can answer. 4 THE WITNESS: Oh. The 5 answer is that at the time when we 6 lifted the hold, we did not have 7 any indications that we had an 8 issue with the Mylan product. 9 BY MR. STANOCH: 10 Q. Can you identify for me any 11 testing for nitrosamines that Teva did at 12 or before the time it lifted the hold on 13 Mylan valsartan API or finished product 14 containing same? 15 A. There was no testing 16 performed because there were no 17 analytical methods that could perform 18 those tests. 19 Q. Earlier you mentioned that 20 Teva didn't have the equipment. 21 Were you referring to gas 22 chromatography equipment? 23 A. That piece of -- that type 24 of equipment was later identified as the</p>	<p>Page 216</p> <p>1 right equipment, analytical equipment, to 2 perform this type of test. 3 Q. Well, it wasn't later on, 4 sir. 5 I mean, Teva's facility in 6 India had a gas chromatography machine, 7 didn't it? 8 A. In order for you to perform 9 the test on these products, you need two 10 things. One is the equipment, but the 11 other thing that you need is the 12 validated analytical test method. So 13 it's not as simple as just saying, here 14 is the equipment, just perform the test. 15 For us to ensure that we 16 would have the right analytical data, we 17 would have to not only find the 18 equipment, you mentioned the equipment, 19 it was an R&D piece of equipment that was 20 located, I think it was in India, but we 21 didn't have validated analytical test 22 methods at the time to perform the type 23 of testing. 24 Q. We'll talk about methods</p> <p>Page 217</p> <p>1 later, sir. 2 But, you know, your answer 3 before, a few questions ago, related to 4 equipment. So I'm focusing on equipment 5 now, all right? 6 A. Okay. 7 Q. And my question was, 8 certainly at this time, in early July 9 2018, Teva had -- in fact, it had, at 10 multiple facilities, gas chromatography 11 equipment, didn't it? 12 A. I don't know how many pieces 13 of equipment we had. 14 But I have to -- again, I 15 have to say that the presence of the 16 equipment itself is not enough for you to 17 conduct the testing. That's all I'm 18 saying. 19 I'm not trying to go into 20 analytical testing. But -- the equipment 21 is one part. But the availability of an 22 analytical test method to perform the 23 testing is also necessary. 24 Q. Sure. Again, I understand</p>
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1 there's two parts to it.
2 And, again, just focusing on
3 the equipment. Teva had the equipment
4 necessary to do a test for nitrosamines
5 in early July 2018, correct?
6 A. The equipment was there. I
7 don't know exactly what their
8 capabilities of the equipment were. I
9 know that they were being used in
10 research and development.
11 So I don't know if we had
12 all the conditions that would be required
13 for that piece of equipment to be fully
14 operational for the purpose of performing
15 finished drug product testing, or even
16 API testing.
17 MR. STANOCH: I'll mark
18 Teva-145, ending Bates 21073.
19 - - -
20 (Whereupon, Exhibit
21 Teva-145,
22 TEVA-MDL2875-00021073-1074,
23 7/13/15 E-mail, Var to
24 Koller-Dette, was marked for

Page 219

1 identification.)
2 - - -
3 BY MR. STANOCH:
4 Q. Tell me when you have that,
5 sir.
6 A. Yes.
7 Q. You have it?
8 A. Yes, I have it.
9 Q. This is a July 13th, 2018,
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 220

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

Page 221

1 A. Yes.
2 Q. And HS-GC, that's HeadSpace
3 gas chromatography with the nitrogen
4 detection?
5 A. Yes.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

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1 (Whereupon, Exhibit
2 Teva-146,
3 TEVA-MDL2875-00020898-0903,
4 7/11/18 E-mail, Barreto to Lyons,
5 was marked for identification.)
6 - - -
7 THE WITNESS: We're ready.
8 BY MR. STANOCH:
9 Q. This exhibit, sir, it's
10 Bates ending 20898.
11 Do you have it in front of
12 you?
13 A. Yes, I do.
14 Q. And this e-mail string,
15 you're at the topmost of this e-mail
16 string, right? You see that?
17 A. Yes.
18 Q. This is July 11, 2018?
19 A. Yes.

■ [REDACTED]

Page 227

■ [REDACTED]

3 A. Do you mind if I read
4 through this?
5 Q. Please. And I'm
6 specifically looking at an e-mail from
7 Munish Var, July 10th, 2018.
8 But take your time and let
9 me know when you're ready.
10 A. Yes. I'm ready to answer
11 your question.

■ [REDACTED]

Page 228

■ [REDACTED]

Page 229

■ [REDACTED]

4 BY MR. STANOCH:
5 Q. You're saying from your
6 perspective any test for nitrosamines in
7 API or finished dose would have to be via
8 a valid -- a validated method; is that
9 what you're telling me?
10 A. That's what I'm saying.
11 Q. And so --
12 A. That's what the regulators
13 would expect of me as the manufacturer.

■ [REDACTED]

24 MS. LOCKARD: Objection.

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1 Misstates testimony.
2 THE WITNESS: What I'm
3 saying is -- what I'm clarifying
4 is that testing activities were
5 being performed toward getting to
6 the point where we could have the
7 test that would be reliable.
8 At that point, so long as I
9 see tests that are being performed
10 by an R&D organization, that is a
11 test that is subjected to being
12 challenged.
13 And it is -- it is a good
14 indicator that we were moving in
15 the right direction. But that
16 does not necessarily mean that at
17 that point we already had all the
18 capabilities that were necessary
19 to perform reliable testing.
20 That's what I'm saying.
21 BY MR. STANOCH:
22 Q. Well, certainly, wouldn't it
23 have been a good indicator to use the
24 same equipment and same analytical method

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1 being used at this Teva India facility to
2 test the Mylan valsartan API, too?
3 A. Again, every API has to be
4 challenged against a specific test
5 method. So even a test method -- a test
6 method is not always a good method for
7 two different APIs. Just the fact that
8 it's, let's say, valsartan; well, the
9 valsartan process for Mylan is different
10 from ZHP and it's different from any
11 other organization. So I still have to
12 ensure that that test method works for
13 every single one of these different APIs.
14 So what I'm trying to say
15 is, we did some work with API batches
16 produced by TAPI India, different
17 tests -- manufacturing processes.
18 Whether that test method would work with
19 any of the other suppliers, this is
20 something that had to be validated, had
21 to be confirmed. That's my point.
22 Q. Did Teva put a hold on its
23 own valsartan API and product that
24 incorporated its own valsartan API that

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1 was being made in the Teva India
2 facility?
3 MS. LOCKARD: Object to the
4 form. Outside the scope of the
5 deposition. Outside of the court
6 discovery order. TAPI API was
7 never sold in the United States.
8 So he's not testifying on that.
9 MR. STANOCH: He can answer
10 individually.
11 MS. LOCKARD: If you have
12 personal knowledge.
13 THE WITNESS: I do not have
14 any information to provide with
15 respect to this -- the Teva API
16 batches.
17 BY MR. STANOCH:
18 Q. As a global quality
19 executive, you don't recall whether you
20 or anyone else put a hold on Teva's own
21 valsartan API?
22 MS. LOCKARD: Objection.
23 Same objections. Outside of the
24 notice of deposition. Outside the

Page 233

1 court discovery order. And it's
2 been asked and answered and
3 objected to.
4 BY MR. STANOCH:
5 Q. Go ahead, sir.
6 MS. LOCKARD: Okay. So it's
7 time for a break.
8 BY MR. STANOCH:
9 Q. You can answer.
10 MR. STANOCH: There's a
11 pending question.
12 THE WITNESS: Well, my
13 answer is that at this point I'm
14 not able to determine the extent
15 to which I can answer your
16 question.
17 MR. STANOCH: One more
18 minute, counsel, all right?
19 MS. LOCKARD: Okay.
20 BY MR. STANOCH:
21 Q. So Teva released its hold on
22 Mylan API -- or valsartan containing that
23 API without doing any testing for
24 nitrosamines, while at the same time

Page 234

1 we've seen that Teva was using its own
2 equipment and doing its own testing of
3 its own valsartan API; isn't that right?
4 A. No.
5 MS. LOCKARD: Objection.
6 Asked and answered.
7 THE WITNESS: No. Two
8 different -- two different
9 situations.
10 Teva, at this point, is
11 trying to determine the extent to
12 which it can develop the test
13 method and whether it has the
14 equipment that is necessary to
15 perform testing.
16 BY MR. STANOCH:
17 Q. And Teva lifting its hold of
18 Mylan API, or product containing therein,
19 without doing any testing of that
20 product?
21 MS. LOCKARD: Objection.
22 Asked and answered.
23 THE WITNESS: I already
24 answered the question.

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1 We released product based on
2 the fact that we had no
3 indications that there was a
4 problem with Mylan product at the
5 time when the decision was made.
6 BY MR. STANOCH:
7 Q. You had no indication
8 because you had done no testing, correct?
9 A. No. We had no indication
10 because the product that we received from
11 Mylan at the time fulfilled all the
12 specifications that were set in the
13 approved submission.
14 Q. Again, you lift the hold on
15 Mylan API, or finished dose containing
16 Mylan API, without conducting any
17 nitrosamine testing, correct?
18 MS. LOCKARD: Objection.
19 Asked and answered.
20 MR. STANOCH: You can
21 answer.
22 THE WITNESS: So we did not
23 perform any testing because we did
24 not have analytical test methods

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1 to perform that type of test at
2 the time.
3 MR. STANOCH: Let's go off
4 the record.
5 VIDEO TECHNICIAN: The time
6 is now 12:16 p.m. Going off the
7 record.
8 - - -
9 (Whereupon, a luncheon
10 recess was taken.)
11 - - -
12 VIDEO TECHNICIAN: The time
13 is now 1:04 p.m. Back on the
14 record.
15 BY MR. STANOCH:
16 Q. Welcome back, sir.
17 Did you talk to anyone
18 besides Ms. Lockard during the break?
19 A. No, only with Mr. Steven
20 Harkins.
21 Q. Understood. That's also
22 outside counsel for Teva?
23 A. Yes.
24 MR. STANOCH: I'm going to

Page 237

1 mark the next exhibit, sir.
2 - - -
3 (Whereupon, Exhibit
4 Teva-147,
5 TEVA-MDL2875-00020853-0854, 7/8/18
6 E-mail, Barreto to Drape, was
7 marked for identification.)
8 - - -
9 MR. STANOCH: Teva-147 is
10 going to be Bates ending 20853.
11 BY MR. STANOCH:
12 Q. Tell me when you can see
13 that, sir.
14 A. I can see it now.
15 Q. Great. This is an e-mail
16 chain, July 8th, 2018, between you and
17 Eric Drape, and Eric Rubin, in fact?
18 A. Yes.
19 Q. Yes.
20 And who is Eric Rubin?
21 A. He is the director of
22 communications for Teva.
23 Q. Here it looks like you and
24 Mr. Drape and Mr. Rubin are communicating

Page 238

1 about a media question-and-answer piece
2 concerning the valsartan API and the
3 nitrosamine contamination, yes?
4 A. Yes.
5 Q. And Mr. Drape asks, in the
6 middle, about the fact that the change
7 was implemented in 2012.
8 Do you see that?
9 A. Yes, I do see that in the
10 report.
11 Q. Right. He's referring to
12 the manufacturing process change at ZHP,
13 right?
14 A. Correct.
15 Q. And then in your e-mail
16 response, among other things, you note in
17 the last bullet, The manufacturing
18 process made in 2012 by the API supplier
19 was not notified to Teva.
20 Do you see that?
21 A. Yes, I see that. It's the
22 last bullet.
23 Q. Right. So correct me if I'm
24 wrong, I thought you said earlier today

Page 239

1 that ZHP had told Teva about the
2 manufacturing process change from the TEA
3 to the zinc chloride method?
4 A. So at the time I put this
5 report together, I was not aware of those
6 details. So that would have been my best
7 understanding at the time. Obviously, if
8 additional information came later on, I
9 was -- I would stand corrected that,
10 indeed, there was a report from ZHP to
11 Teva.
12 Q. So at the time, in July
13 2018, when you're e-mailing with your
14 boss, Eric Drape, you were telling him
15 that ZHP had not shared with Teva
16 information about the manufacturing
17 process change at ZHP for the valsartan
18 API, right?
19 A. And that -- that was
20 incorrect.
21 Q. Right. And you're telling
22 me you've since learned that Teva did
23 become aware of the change in the
24 process?

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1 A. Yes. I told you that we
2 became aware of the process.
3 Q. And are you speaking to Teva
4 becoming aware or sort of legacy Actavis,
5 or both? What do you mean?
6 A. So in 2012, that would have
7 been -- I'm trying now to look into the
8 history. It could have been the legacy
9 Actavis. That might have been the case,
10 yes.
11 Q. When did you learn that this
12 bullet here in your e-mail to Eric Drape
13 was inaccurate?
14 A. I'm trying to remember now
15 exactly when -- when that happened.
16 Probably when I saw the
17 investigation report that they sent us.
18 Q. The investigation report
19 that ZHP sent to Teva?
20 A. Correct.
21 Q. In 2018?
22 A. In 2018, correct.
23 Q. So you believe that ZHP,
24 sometime in 2018, sent a report to Teva

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1 which noted somehow that ZHP had shared
2 the manufacturing process change at an
3 earlier date with Teva?
4 A. That is correct.
5 Q. Do you recall when you saw
6 that investigation report?
7 A. That must have been a couple
8 of weeks --
9 MS. LOCKARD: Don't
10 speculate.
11 THE WITNESS: Yes. I don't
12 recall. I don't recall.
13 BY MR. STANOCH:
14 Q. You saw -- go ahead.
15 A. It must have been sometime
16 during July.
17 Q. July of 2018?
18 A. Yes, sir.
19 Q. Sitting here today, can you
20 describe the report that you're thinking
21 of, what it would look like?
22 A. It's a report where ZHP
23 provides an explanation with respect to
24 the assessment they did of the situation

Page 242

1 and the way in which they confirmed that
2 the -- they confirmed -- they established
3 a root cause for the presence of
4 nitrosamines.
5 Q. Do you recall that report
6 specifically mentioning that ZHP had told
7 Teva or legacy Actavis about the change
8 in manufacture back in 2012?
9 A. I'm trying to remember if it
10 was in that report or if it was later on.
11 Again, I'm trying to remember now. I'm
12 speculating. Because I don't recall if
13 it's specifically in that report.
14 Q. Do you think it might be in
15 another report that you saw after July
16 2018?
17 A. Oh, yes. It may have
18 been -- yeah, I saw all the reports. For
19 instance, the response that they had to
20 the 483, I think it mentioned something
21 about that as well.
22 Q. You think -- you think ZHP's
23 response to the FDA's 483 concerning the
24 agency's inspection of ZHP mentions that

Page 243

1 ZHP had shared the manufacturing change
2 with Teva or legacy Actavis in 2012?
3 A. I -- that's, again, I would
4 be speculating. But I know I saw that
5 information in one of those reports.
6 Q. And I'm just trying to
7 narrow it down, to the best you can
8 recall, what report you think is the
9 basis for you saying you were wrong in
10 this e-mail to your boss back in July
11 2018.
12 Is there any other things
13 besides the ZHP response to the FDA's
14 Form 483?
15 A. Yeah. It's the audit report
16 that actually was generated around the
17 time when the change was established.
18 That information is also documented
19 there.
20 Q. That would be what, the ZHP
21 or an Actavis audit report of ZHP?
22 A. It would have -- it would
23 have been an Actavis audit report.
24 Q. So you think an Actavis

Page 244

1 audit report from the 2012 timeframe
2 makes note of it?
3 A. '12, '13. I'm trying to
4 remember now.
5 MS. LOCKARD: Can I clarify
6 for the record? It's not an audit
7 report, but there's a change
8 control document at Teva. And
9 that's what he's referencing.
10 THE WITNESS: We saw that
11 change control, yes. I've seen
12 it.
13 But I also saw the
14 statements in the audit report.
15 Yes.
16 MS. LOCKARD: I just want to
17 make sure you're not referring to
18 that as an audit report.
19 THE WITNESS: Yes. Thank
20 you.
21 MS. LOCKARD: I'll butt out,
22 sorry. I'm trying to be helpful.
23 MR. STANOCH: Thanks for
24 trying, counsel.

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1 BY MR. STANOCH:
2 Q. So now, per Ms. Lockard, we
3 think maybe it's a change control
4 document at Teva that mentions it, as
5 well as maybe an Actavis audit report
6 from the 2012, 2013 time period?
7 A. Yes.
8 Q. When do you recall first
9 seeing those documents?
10 A. I don't recall now. It was
11 a long time ago.
12 Q. Was it before or after this
13 litigation started?
14 A. It was before.
15 Q. Was the change control
16 document to Teva or to Actavis?
17 A. There is a change control
18 document at Teva that outlined the
19 process steps that were taken to process
20 the change control from receipt all the
21 way through closure.
22 Q. That was classified as a
23 minor change; is that right?
24 A. Correct.

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1 Q. Does that mean --
2 A. Minor to moderate.
3 Q. Right. Which meant that it
4 didn't need a prior approval by a
5 regulatory agency for Teva to adopt that
6 change by ZHP, right?
7 A. Yes. And what it meant was
8 that we filed a CBE 30 to the agency once
9 the entire process, including the change
10 control requirements were completed.
11 Q. And at that time, Teva, or
12 legacy Actavis, neither conducted their
13 own testing of the valsartan API
14 material, they only reviewed the work
15 that was done by ZHP, correct?
16 A. There was testing conducted
17 by Teva according to the specifications
18 that were in place.
19 Q. By Teva or legacy Actavis?
20 A. Well, sorry. By legacy
21 Actavis. I'm saying "Teva" meaning that
22 I'm speaking on behalf of Teva right now.
23 Q. I understand. I appreciate
24 that, sir.

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1 Because we're talking back
2 in time, prior to the integration, I just
3 wanted to be precise, that's all.
4 A. Understood.
5 Q. Otherwise, you've been doing
6 an excellent job in terms of how you're
7 referring to Teva currently or post
8 integration.
9 A. Thank you. I appreciate
10 that.
11 Q. The only testing that legacy
12 Actavis would have done would have been
13 that set forth in the specification at
14 the time, right?
15 A. The specifications. They
16 were also part of the filing with the
17 ANDA, yes.
18 Q. And none of those
19 specifications related to testing for
20 nitrosamines, correct?
21 A. That is correct.
22 Q. And none of those
23 specifications, in fact, called for gas
24 chromatography testing of the API, did

Page 248

1 it?
2 A. That is correct.
3 Q. It was all HPLC,
4 high-performance liquid chromatography,
5 correct?
6 A. That is correct, which is
7 the USB test method that we are bound to
8 follow.
9 Q. And you're not aware of
10 whether Teva or ZHP, at the time of the
11 change control in 2012, did any gas
12 chromatography testing of the valsartan
13 API post change TEA to zinc chloride?
14 A. I have not seen any
15 documented activity around that.
16 Q. Is -- one moment.
17 Was Teva, in 2012,
18 purchasing valsartan API from ZHP itself,
19 apart from legacy Actavis at that time?
20 A. I'm not aware of that.
21 MR. STANOCH: I'm going to
22 mark the next exhibit, sir.
23 - - -
24 (Whereupon, Exhibit

Page 249

1 Teva-148,
2 TEVA-MDL2875-00549865-9886, 7/9/18
3 E-mail, Osmian to Baeder, was
4 marked for identification.)
5 - - -
6 MR. STANOCH: Teva-148.
7 It's Bates ending 549865.
8 BY MR. STANOCH:
9 Q. Let me know when you have
10 it.
11 A. I have it.
12 Q. This appears to be a July
13 9th, 2018, e-mail from Michelle Osmian,
14 and it's attaching various final
15 documents.
16 Do you see that?
17 A. I'm looking at it, yes.
18 Q. And you can -- the documents
19 should be behind the e-mail. One is the
20 health hazard assessment for valsartan
21 40, 80, 160, 320.
22 Do you see that?
23 A. I see that.
24 Q. And then I believe there is

Page 250

1 a similar, if not identical, assessment
2 for the valsartan hydrochlorothiazide
3 products?
4 A. Yes.
5 Q. And then there's the
6 toxicological assessment for NDMA in
7 valsartan drug substances.
8 Do you see that one?
9 A. Yes.
10 Q. And this looks like it's the
11 final one signed by Dr. Nudelman, right?
12 A. I'm getting there.
13 Q. Sure.
14 A. I'm looking for the one that
15 is signed by Dr. Nudelman.
16 Where would you say that you
17 have the document of Dr. Nudelman?
18 Q. Unfortunately, I can't -- it
19 wasn't produced with Bates numbers. I'll
20 just --
21 A. Oh, I see. No problem.
22 Okay. Right.
23 Oh, I found it.
24 Q. Good. And then the next

Page 252

[REDACTED]

Page 251

1 document is something called a global
2 quality report.
3 Do you see that?
4 A. Yes.
[REDACTED]

Page 253

[REDACTED]

Page 254

1 report.
2 Q. A genotoxic potential
3 impurity wasn't important enough, on June
4 20th, on its own, to tell the agency,
5 right?
6 A. That is not --
7 MS. LOCKARD: Object to
8 form. Argumentative.
9 THE WITNESS: That is not
10 what I'm saying.
11 It is an important activity.
12 But in order to report it to the
13 FDA, we still need to gather more
14 information.
15 BY MR. STANOCH:
16 Q. Nothing prevents Teva from
17 updating its field alerts to the FDA,
18 correct?
19 A. But from my experience,
20 presenting a field alert report to the
21 FDA that is incomplete, it's also not a
22 good reflection of the responsibility
23 that we have for reporting.
24 Q. And is it a good reflection

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1 on the responsibility to know about a
2 genotoxic impurity that your -- the
3 customers and consumers are taking and
4 not telling anyone about it?
5 MS. LOCKARD: Object to the
6 form. Argumentative.
7 THE WITNESS: Again, from my
8 experience, my focus is on making
9 sure that once information is
10 provided, that we can gather as
11 much information as we can.
12 So even on June 20th, if
13 this information had been given,
14 that would not have immediately
15 triggered a field alert at that
16 point with that amount of
17 information.
18 BY MR. STANOCH:
19 Q. Are you saying that based on
20 the GMP regulations or Teva's own SOP on
21 field alert or both?
22 A. Based on the understanding
23 that we have of the purpose of field
24 alert reports.

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1 Allegations are made every
2 day about certain things, and the purpose
3 of the field alert report is to clearly
4 state to the FDA that you have a reason
5 to suspect that product in distribution
6 is -- may be affected by a quality issue.
7 In this case, what we had
8 was, in my opinion, not sufficient for us
9 to move on with the field alert report.
10 In my opinion, we needed more
11 information.
12 Q. Does Teva's field alert
13 reporting corporate policies, 0053, that
14 we looked at earlier state that you must
15 identify a genotoxic impurity
16 specifically before informing the FDA
17 about it?
18 A. That's not what I'm saying.
19 What I'm saying is that the facts around
20 the reporting, the location of that
21 impurity, how it was potentially found,
22 what -- if there was a testing done, what
23 did the testing indicate, what was the
24 impurity itself, that's all I'm saying.

Page 257

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
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20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 258

[REDACTED]

Page 259

[REDACTED]

Page 260

[REDACTED]

3 Q. My question a couple -- ago

4 was whether or not Teva had procedures in

5 place with ZHP to ensure that information

6 regarding the potential impurities were

7 immediately shared with Teva?

8 A. In terms of the procedures

9 in place, if you're referring to a

10 quality agreement, I think there was a

11 quality agreement between Teva and ZHP.

12 Q. Or any procedure, whether

13 it's in a quality agreement or otherwise.

14 Was there any procedure in

15 place, of any nature, concerning the

16 process and timeline for which ZHP would

17 need to inform Teva about an issue such

18 as a genotoxic impurity in valsartan API?

19 A. I cannot think of any other

20 procedures within Teva. But I'm sure

21 there are procedures within ZHP that

22 would indicate, you know, they would have

23 that level of responsibility, whenever

24 they find something that would have

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1 impact on product safety, quality and

2 efficacy, to report to the customers.

3 Q. Well, you're not testifying

4 on behalf of ZHP today, right?

5 A. I am not.

6 Q. Right. And you can't speak

7 to ZHP's procedures in place as of 2018,

8 can you?

9 A. I cannot speak to those.

10 Q. All right. You didn't

11 review any of those procedures at the

12 time back in June 2018, did you?

13 A. No.

14 But what I'm trying to say

15 is that, based on the actions that ZHP

16 did perform of notifying Teva, they must

17 have had some kind of a process in place

18 to ensure that the customers were

19 notified.

20 Q. And all I'm getting at, sir,

21 is you're just speculating at that, you

22 haven't actually seen what the process

23 is?

24 A. That is correct.

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1 And today, you know, it is
2 very clear that it is not possible
3 to manufacture product that could
4 be, you know, totally free from
5 nitrosamines. So there are
6 specifications now in place for
7 these products.
8 BY MR. STANOCH:
9 Q. Nothing in my question was
10 regarding whether patients should keep
11 taking the drug, right?
12 Did you hear anything like
13 that in my question, sir?
14 MS. LOCKARD: Objection.
15 That's argumentative.
16 BY MR. STANOCH:
17 Q. Did you hear me ask anything
18 about that, sir?
19 A. No.
20 But I wanted to clarify that
21 the FDA's position actually changed and
22 evolved in the process, the same way that
23 everything else evolved, in terms of, you
24 know, the view that we all had on the

Page 267

1 impact of these impurities.
2 So it went from zero to
3 tolerable levels. So it just -- it
4 didn't -- at the time, it was not a
5 stable situation.
6 Q. Sure. And this will go
7 quicker for all of us if you follow my
8 syllogisms, sir, because where I was
9 going was, the FDA ultimately ended up
10 with 0.3 parts per million, correct; do
11 you recall that, for NDMA?
12 A. Correct.
13 Q. All right. So we can say
14 that ZHP's recommendation -- or
15 conclusion, at least as of the date of
16 this report in July 2018, was, what, ten
17 times more NDMA it was saying was
18 permissible, is that right, than what is
19 the current limit today?
20 A. I think it's 96 nanograms
21 per day, if I'm not mistaken.
22 Q. 31.2 parts per million is
23 much more than 0.3 parts per million,
24 right?

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1 A. Of course. That was the
2 assessment they did at the time. There
3 were no specifications in place at the
4 time, so -- yeah.
5 Q. And we saw documents where
6 some of Teva's own people, like Dr.
7 Nudelman, were calling ZHP's assessment
8 unacceptable when it came to evaluating
9 NDMA, right?
10 A. I'm not in a good position
11 to, you know, challenge one way or the
12 other.
13 But I think that during the
14 discussions we had, there was a -- the
15 discrepancy was more around the way in
16 which data was going to be -- was being
17 interpreted and how certain, you know,
18 calculations were to be -- were to be
19 applied.
20 [REDACTED]

Page 269

21 [REDACTED]

Page 270

[REDACTED]

Page 272

[REDACTED]

6 We knew that the situation
7 was evolving. So we knew that as new
8 information was generated, then we would
9 revise our position with respect to these
10 activities, which we did.
11 Q. Teva wasn't testing any
12 finished dose of valsartan, right?
13 A. Teva was testing the
14 valsartan product according to the
15 established specifications. Because as I
16 said to you this morning, there's no
17 validated analytical test method that we
18 could rely on to do that testing.
19 Q. I should have been more
20 precise.
21 I'm talking about, Teva
22 wasn't testing any valsartan finished
23 dose for the presence of nitrosamines
24 after June 2018?

Page 271

[REDACTED]

Page 273

1 A. Teva was not testing for
2 nitrosamines because we did not have an
3 analytical test method for NDMA in the
4 finished product.
5 Q. In fact, Teva was -- and you
6 specifically did not want to test
7 valsartan finished-dose products; is that
8 fair?
9 A. That is -- that is not
10 exactly correct.
11 What we decided at the time
12 was that, based on the tests that were
13 being performed on API, then we would use
14 the information from the API to then
15 establish the -- what would be the
16 concentration of nitrosamines in finished
17 product if any impurities were found in
18 the API.
19 So we have the ability to
20 make an extrapolation in the absence of
21 the test method. We would -- we would
22 concentrate on using the data from the
23 API to actually determine what would be
24 the concentration of any of these

Page 274

1 impurities in the finished product.
2 Q. And that's, in fact, what
3 Teva ultimately did, right? It tested
4 valsartan API and then made conclusions,
5 which it ultimately shared with the FDA,
6 about the NDMA concentrations in
7 finished-dose valsartan?
8 A. And that was the most
9 practical approach, because one API could
10 be used to manufacture a certain number
11 of finished drug products. So we would
12 have the ability to cover as many
13 finished drug products as we could.
14 Q. And there's a lot of
15 reference -- and I can pull documents
16 up -- about whether or not Teva was going
17 to test United States product or not.
18 Do you recall any of that?
19 A. The reason why we -- yes, I
20 do.
21 And the reason for that was
22 that we had already recalled all the
23 product from the United States. So for
24 us, the question was, now that we don't

Page 275

1 have any product in distribution, what is
2 the immediate necessity to test product
3 in the United States?
4 Q. Well, it was -- you recalled
5 the product in the United States. I
6 mean, it was still within expiration,
7 some of it, right?
8 A. Yes.
9 Q. And certainly -- don't you
10 think the best way to know the
11 concentrations of NDMA in finished-dose
12 valsartan would be to test the actual
13 finished-dose valsartan?
14 A. Ideally, yes. But as I
15 indicated to you, every analytical test
16 method has to be developed and validated
17 for each specific formulation.
18 So for us, the focus was
19 really to concentrate on API testing,
20 because that would give us a much -- an
21 expedient process and way, approach, to
22 get to the information that we wanted to
23 obtain.
24 Q. And it was Teva's position

Page 276

1 that extrapolating the nitrosamine test
2 results of the API to the valsartan
3 finished dose was appropriate?
4 A. In our position, that was
5 appropriate, yes.
6 Q. Do you recall working on a
7 valsartan testing strategy?
8 A. Yes.
9 Q. Okay. What was the purpose
10 of that document?
11 A. So the valsartan testing
12 strategy, if I recall well, was intended
13 to find a way whereby we could put
14 together conditions that would allow us
15 to test valsartan API, valsartan finished
16 product eventually. If you're talking
17 about the same thing.
18 Q. I will put up an exhibit,
19 sir, and you can tell me if this is what
20 you were thinking of.
21 MR. STANOCH: Teva-50 --
22 strike that. Teva-149 will be
23 Bates ending 42637.
24 - - -

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1 (Whereupon, Exhibit
2 Teva-149,
3 TEVA-MDL2875-00042637-2649,
4 8/14/18 Valsartan Testing
5 Strategy, was marked for
6 identification.)
7 - - -
8 THE WITNESS: Just give me
9 one second. I'm trying to get to
10 that.
11 149 you said?
12 BY MR. STANOCH:
13 Q. Correct, sir.
14 A. Okay. Thank you.
15 May I just look at it for a
16 second?
17 Q. Sure, sure.
18 A. Yes.
19 As I indicated to you, it
20 was a strategy to pursue testing of both
21 API and finished product.
22 Q. Right. And this is a draft,
23 I understand that.
24 But it looks like there's a

Page 280

¹ number of comments that you have made.
² For example, on Page 3 of 13, Bates
³ ending 42639.

⁴ A. Okay. Page 3?

5 Q. Yes.

⁶ A. Comment DB5?

⁷ Q. Yes.

⁸ A. And what's the question?

9 Q. Right. I mean, that was one
10 of your comments to this draft testing
11 strategy document, right?

12 A. Yes.

[REDACTED]

11 Q. And Mylan, for example,
12 submitted some justification to Teva for
13 its belief that NDMA could not form in
14 its valsartan product, right?

15 A. NDMA, yes. And NDEA later
16 on.

17 Q. And that was a submission
18 sometime in mid August 2018, right?

19 A. Yeah. I think around that
20 very same time, if I'm not mistaken, we
21 had received information from Swissmedic
22 which indicated that they had tested
23 samples from Mylan and that product from
24 Mylan was not found to contain the

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[illegible]¹ impurity.

2 So, again, it goes back to
3 the strategy -- the intent of the
4 strategy is focus on those APIs that you
5 suspect or have confirmed that could have
6 this issue.

7 Q. How many valsartan APIs was
8 Teva purchasing?

9 A. So I'm aware of ZHP. Mylan.
10 I think we were acquiring from Jubilant.
11 And what was the other one? But those
12 were not for the U.S.

13 So for the U.S., we were
14 only talking about ZHP and Mylan.

15 Q. Right. So there's only --
16 Teva was only purchasing valsartan API
17 from ZHP and Mylan for U.S. market
18 product, right?

19 A. Yes.

20 Q. And Teva had already, by
21 this time in August 2018, had placed a
22 hold on the ZHP API or the finished dose
23 containing it, right?

24 A. Correct.

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1 Q. So, then, the only other --
2 only other company is Mylan, then, for --
3 vis-à-vis the U.S. market, right?
4 A. That's correct.
5 Q. And Teva, even by -- we
6 looked at it earlier, Teva did not test
7 Mylan API itself, at least as of August
8 2018, right?
9 A. We did not test. But,
10 again, we asked for the certification
11 from them and then we also had that
12 information from Swissmedic that gave us,
13 at the time, a certain level of assurance
14 that the Mylan product was not within the
15 scope of the investigation.
16 Q. Well, Swissmedic, that was
17 testing product in the European market, I
18 assume, yes?
19 A. Yes.
20 But Swissmedic is testing
21 product from Mylan, which is valsartan
22 product. The finished product is for the
23 European market in that case, but the API
24 comes from Mylan.

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1 Q. Right. And it's a different
2 formulation; it's not the same VLN
3 process for the U.S. market that was
4 going to Teva Jerusalem, correct?
5 A. I do not -- I cannot say
6 it's a different process or the same
7 process. I would be speculating at this
8 time.
9 Q. You're not sure one way or
10 the other?
11 A. Correct.
12 Q. And this Swissmedic
13 communication, when do you think it
14 happened?
15 A. I want to say sometime the
16 middle of August.
17 Q. So by middle of August, Teva
18 had not done any testing itself of Mylan
19 API, and Mylan had not provided any test
20 results of its valsartan API to Teva.
21 It just said, it can't form
22 because of the process we use; is that
23 right?
24 A. We had that preliminary

Page 284

1 information where they confirmed that.
2 They didn't use DMF, which we knew would
3 be an important factor in the
4 formulation. So that was an important
5 piece of information for us.
6 Q. And I'm just focused,
7 laser-focused, on test results right now,
8 Mr. Barreto.
9 So as of August 2018, Teva
10 had not tested valsartan API from Mylan
11 for nitrosamines itself, right?
12 A. That is correct.
13 Q. And also by August 2018,
14 Mylan had not provided any test results
15 of its valsartan API for nitrosamines to
16 Teva?
17 A. That is correct.
18 Q. The only thing that Mylan
19 provided was a justification saying, we
20 don't use DMF so NDMA can't form in our
21 process, right?
22 A. But I wouldn't say that was
23 the only thing. It's an important
24 technical piece of information.

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1 Because in order for you to
2 have impurity, you have to have certain
3 conditions that are present. Without
4 those conditions, then you will not have
5 the impurity. So we -- that was an
6 important piece of information.
7 Q. Ultimately, at some point,
8 though, Teva did test Mylan API and found
9 that it contained, in some instances,
10 NDMA; isn't that right?
11 A. I think so.
12 Q. So why, in August 2018, was
13 it good enough for Teva to take Mylan's
14 word for it without doing the testing
15 itself?
16 A. As I indicated to you, at
17 the time when we received the
18 confirmation from them that the DMF was
19 not present in the process, you know, our
20 technical experts were comfortable with
21 the fact that if the manufactured process
22 is not prone to generating impurity, we
23 should not expect impurity to be present.
24 Q. We talked about earlier,

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1 though -- we looked at the e-mail that
2 said that Teva's people said they
3 couldn't do an evaluation because they
4 didn't have the full route of synthesis,
5 right?
6 Do you remember the
7 document?
8 A. We didn't have a full
9 evaluation of the route of synthesis,
10 you're correct.
11 However, Mylan did provide a
12 certification that, in their process,
13 they were not using DMF.
14 Q. And Teva believed it was
15 sufficient for Teva to take Mylan's word
16 for it that nitrosamines can't formulate
17 in the valsartan API that Mylan was
18 selling to Teva?
19 A. Within the process that we
20 were running at that point in time, we
21 felt that we had information from Mylan
22 that would allow us to continue with the
23 process.
24 However, the process didn't

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1 stop there. I mean, we are monitoring
2 the situation, we continue to receive
3 information from different sources.
4 So -- and, eventually -- you know, Mylan
5 continued to communicate with us.
6 Q. Did the justification that
7 Mylan provided to Teva identify all of
8 the solvents that it was using in the
9 valsartan API manufacturing process?
10 A. Can you repeat the question?
11 Q. Did the justification Mylan
12 provided to Teva include a discussion of
13 all the solvents Mylan was using in the
14 valsartan API manufacturing process?
15 A. I don't remember. But I
16 would not necessarily expect that they
17 would get into that type of detail --
18 Q. Would you be surprised if
19 Mylan's justification made no mention of
20 whether it was using fresh or recycled
21 solvents in its valsartan API
22 manufacturing process?
23 A. I'm sorry, what's the
24 question?

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1 Q. Would you be surprised to
2 hear that Mylan did not make any
3 indication whether it was using fresh or
4 recycled solvents in its valsartan API
5 manufacturing process?
6 A. Not necessarily. I mean, it
7 is -- it is common practice, within the
8 industry, to use both fresh and recovered
9 solvents. So that would not necessarily
10 indicate that Mylan was doing something
11 that was unacceptable.
12 Q. In your -- in your
13 preparation for today, did you see
14 anything suggesting that Teva knew that
15 Mylan was using recovered solvents in its
16 valsartan API manufacturing process?
17 MS. LOCKARD: As of what
18 date?
19 THE WITNESS: Yeah.
20 MS. LOCKARD: Objection.
21 Vague.
22 BY MR. STANOCH:
23 Q. Did you see any information
24 suggesting that Teva knew, prior to June

Page 289

1 2018, that Mylan was using recovered
2 solvents in the valsartan manufacturing
3 process for the API it was selling to
4 Teva?
5 A. It is possible that we knew
6 of the existence of the use of solvent --
7 recovered solvents. However, even during
8 an audit, or through other sources, if
9 this information was known and it was
10 shared with us, that would not have
11 necessarily generated any sort of concern
12 with respect to the extent to which the
13 use of those recovered solvents could
14 represent a problem in any production
15 process.
16 Q. I'm not asking for the scope
17 of any concern, Mr. Barreto.
18 I'm just asking if you're
19 aware of any information, prior to June
20 2018, suggesting that Teva knew that
21 Mylan was using recovered solvents in the
22 valsartan API manufacturing process?
23 A. I do not recall. I am --
24 more than likely, like I said, during the

Page 290

1 audit process, the auditors may have
2 reported it -- and I don't recall now --
3 that recovered solvents were used. And
4 that would have been -- yeah, normal.
5 Q. Do you recall -- strike
6 that.
7 As part of Teva's risk
8 assessment for nitrosamines, does Teva
9 ask the API suppliers to identify all of
10 the key starting-material suppliers?
11 A. As far as the risk
12 assessment we were doing in response to
13 this issue?
14 Q. Yes.
15 A. I don't -- I'm trying to
16 remember. From my understanding, I think
17 the main focus was around the route of
18 synthesis, not necessarily around the
19 intermediates or other starting materials
20 that were used. I think -- I think the
21 main focus of my interest was route of
22 synthesis.
23 Q. Right. The route of
24 synthesis that Teva didn't know about

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1 when all these recalls started, right?
2 You can -- strike that.
3 Teva could have had a
4 quality agreement in place with Mylan
5 that required Mylan to share the route of
6 synthesis for valsartan API with it; is
7 that correct?
8 A. I would say that's
9 incorrect. As I indicated before, most
10 companies will not share their detailed
11 route of synthesis with a company that is
12 purchasing product from them. There are
13 many considerations, including
14 competition.
15 So I don't see how that
16 could happen through a quality agreement.
17 Q. You don't -- you can't think
18 of any instance in which Teva had a full
19 route of synthesis for API it was
20 purchasing from a supplier?
21 A. That may be a possibility,
22 but I don't know.
23 Q. As part of Teva's risk
24 assessment for nitrosamine, did Teva look

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1 to see whether or not any other valsartan
2 API supplier was sourcing materials from
3 ZHP?
4 A. Yes. We were looking at the
5 extent to which intermediates that were
6 generated by ZHP were used in other
7 facilities.
8 Q. Does Teva have -- strike
9 that.
10 Prior to July 2018, did Teva
11 have procedures in place to ensure that
12 its API suppliers were properly
13 performing chromatography and assay
14 testing?
15 A. Yes.
16 Q. And is it your understanding
17 that Teva required its API suppliers to
18 adhere to those procedures?
19 A. Yes.
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 293

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
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9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 Q. Is it your understanding
17 that ZHP's chromatography and assay
18 methods did indicate the presence of
19 NDMA?
20 A. My understanding is that
21 they did not, because the test method
22 they were using, which were the USB test
23 methods, would not allow them to detect
24 the impurities.

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1 Q. The FDA had a different
2 view, correct?
3 A. I understand that's the
4 case.
5 Q. Right. In fact, the FDA
6 stated that -- let's mark it.
7 Do you recall e-mails about
8 this? I'm sure you do, right?
9 A. Excuse me?
10 Q. Do you remember e-mailing
11 with Mr. Drape about the FDA's findings
12 concerning ZHP?
13 A. Can you show me the report?
14 Q. Teva-150, Bates ending
15 67084. Tell me when you have it.
16 - - -
17 (Whereupon, Exhibit
18 Teva-150,
19 TEVA-MDL2875-00067084-7087,
20 12/13/18 E-mail, Drape to Barreto,
21 was marked for identification.)
22 - - -
23 BY MR. STANOCH:
24 Q. This e-mail chain between

Page 295

1 you and Mr. Drape, topmost message is
2 December 13, 2018.
3 The second message is from
4 you to Mr. Drape on December 11th, 2018,
5 right?
6 A. Yes.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
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24 [REDACTED]

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1 [REDACTED]
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3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 Q. And by this time, in
10 December 2018, had Teva conducted its own
11 testing of the ZHP valsartan API?
12 A. By December 2018? I'd have
13 to double check. I think we may have
14 been there at the time.
15 Q. We can go through the
16 documents. That's fine. It's not a
17 memory test, sir.
18 A. Thank you.
19 Is that going to be a new
20 document?
21 MR. STANOCH: Why don't we
22 just take a few-minute break and
23 let me sort of organize, so I can
24 have documents to assist you.

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1 THE WITNESS: Okay. Okay.
2 Sounds good.
3 VIDEO TECHNICIAN: The time
4 is now 2:06 p.m. Going off the
5 record.
6 - - -
7 (Whereupon, a brief recess
8 was taken.)
9 - - -
10 VIDEO TECHNICIAN: The time
11 is now 2:24 p.m. Back on the
12 record.
13 BY MR. STANOCH:
14 Q. Welcome back, Mr. Barreto.
15 A. Thank you.
16 Q. So do you recall when Teva
17 notified the FDA about NDEA contamination
18 in valsartan drugs?
19 A. Yes.
20 MR. STANOCH: I'm going to
21 mark an exhibit, sir. Teva-151.
22 - - -
23 (Whereupon, Exhibit
24 Teva-151, TEVA-MDL2875-00731926,

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1 NDA/ANDA Field Alert, was marked
2 for identification.)
3 - - -
4 MR. STANOCH: Bates ending
5 731926.
6 BY MR. STANOCH:
7 Q. It should be the field
8 alert, sir, when you get it.
9 A. Yes, I'm looking for it.
10 You said 151, correct?
11 Q. Yes.
12 A. Yes. I'm in front of it.
13 Q. This looks to be the same
14 form we saw this morning about the field
15 alert about ZHP's NDMA impurity, right?
16 A. Yes.

■ [REDACTED]

Page 299

■ [REDACTED]

Page 300

■ [REDACTED]

4 Q. Teva was aware of potential
5 NDEA impurities in valsartan and other
6 sartans prior to November 5th, 2018;
7 isn't that right?
8 A. I think so. I think yes.
9 Q. And despite that knowledge,
10 Teva did not do any testing of its own on
11 the Mylan valsartan API, or Teva's
12 finished dose incorporating that API,
13 until after Swissmedic reached out to
14 Teva in November of 2018; is that
15 correct?
16 A. That is correct.
17 But, again, it goes back to
18 the fact that we had previously received
19 information from Swissmedic that they had
20 tested Mylan product and they had not
21 previously reported finding neither NDMA
22 nor NDEA in the product.
23 Q. Teva was aware, though, of
24 the potential for NDEA contamination in

Page 301

1 valsartan product as early as August
2 2018, right?
3 A. That -- that should be
4 correct. And we're speaking now about
5 that being the case with ZHP.
6 Q. Right. So, for example --
7 MR. STANOCH: I'll mark the
8 next exhibit, Teva-152, which is
9 Bates ending 73603.
10 - - -
11 (Whereupon, Exhibit
12 Teva-152,
13 TEVA-MDL2875-00073603-3612,
14 11/16/18 E-mail, Redmond to
15 Barreto, was marked for
16 identification.)
17 - - -
18 MR. STANOCH: It's a
19 November 2018 e-mail from Michael
20 Redmond to you and others.
21 BY MR. STANOCH:
22 Q. Do you see that?
23 A. I'm looking at it, yes.
24 Q. And it's drafting a response

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1 to the Icelandic authorities, right?

2 A. Yes.

3 Q. And if you flip it over to

4 the first page -- are you there?

5 A. Yes.

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[REDACTED]

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[REDACTED]

23 Q. Are you aware that the

24 different regulatory authorities

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1 globally had reached out to Teva in

2 August and September 2018 about potential

3 NDEA impurities in valsartan and other

4 sartan products?

5 A. Yes.

6 Q. So, again, there's multiple

7 instances in which Teva was informed by

8 third parties about the potential for

9 NDEA contamination in valsartan APIs,

10 right?

11 A. That is correct.

12 But, as I indicated to you,

13 we also had information from, in this

14 case, Swissmedic where they had

15 specifically tested valsartan API from

16 Mylan, and they had indicated that the

17 product did not have any nitrosamine

18 impurities.

19 Q. Well, it looks like, then,

20 that Teva didn't tell the FDA about NDEA

21 impurities until Swissmedic told Teva

22 about it; is that fair?

23 A. Can you repeat the question?

24 Q. It looks like Teva did not

Page 305

1 tell the FDA about NDEA impurities until

2 Swissmedic told Teva?

3 A. We told the FDA about NDEA

4 when we came to the information that the

5 Mylan product which was shipped to the

6 U.S. contained NDEA.

7 Q. The Mylan justification we

8 talked about earlier in August 2018, that

9 only spoke to NDMA; isn't that right?

10 A. That is correct.

11 Q. And we've looked at now

12 this -- at least this one document about

13 Iceland, and we've talked about others,

14 where Teva was aware of the potentiality

15 of NDEA contamination in August 2018 as

16 well, yes?

17 A. Yes.

18 Q. So Teva never followed up

19 with Mylan for a justification about NDEA

20 impurities in the Mylan valsartan API,

21 did it?

22 A. It's not that we did not

23 follow up with them. The information

24 they gave us was around NDMA, you're

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1 correct.
2 And, again, because of all
3 the information that we had with respect
4 to Mylan, that it was free from this
5 impurity, at that time there was no
6 reason for us to necessarily go back to
7 Mylan.
8 Although we may have gone --
9 I don't remember now, but we may have
10 pursued a follow-up with Mylan. I don't
11 recall.
12 Q. So you don't recall whether
13 Teva ever asked Mylan to perform testing
14 for NDEA in valsartan API being sold to
15 Teva; is that fair?
16 A. That would be fair.
17 But, again, when the
18 analysis was done for Mylan, we asked
19 them, remember, to give us a
20 certification for route of synthesis and
21 they did not use DMF.
22 So at the time, we did not
23 have as much knowledge, even though we
24 had some knowledge, as to how NDEA could

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1 be formed.
2 So I don't recall again --
3 but it was an evolving process. So it is
4 highly possible that one of us within the
5 corporate group that was monitoring the
6 situation could have requested a
7 follow-up call with Mylan. I just don't
8 remember.
9 Q. And I'm not asking about --
10 for you to speculate, sir.
11 I'm just asking you, sitting
12 here today as Teva's corporate designee
13 and former vice president of quality,
14 whether you know, one way or the other,
15 whether anyone at Teva ever asked Mylan
16 for information concerning NDEA
17 impurities in the valsartan API Mylan was
18 supplying to Teva?
19 A. And my answer is I don't
20 remember.
21 Q. And you had also mentioned
22 the information that Mylan had provided.
23 That was information
24 provided in August of 2018 concerning

Page 308

1 NDMA, correct?
2 A. Correct.
3 Q. None of the information
4 provided in August 2018 related to NDEA,
5 or any other nitrosamine for that matter;
6 is that right?
7 A. That's right.
8 And to the knowledge that we
9 had at the time, the potential formation
10 on the nitrosamines, again, required a
11 certain level of conditions. So, again,
12 the knowledge was evolving at the time.
13 In August, we are still
14 evolving in terms of understanding, you
15 know, how many of these impurities are
16 actually being formed and how and where.
17 Q. Well, you know, the burning
18 question that people are going to want to
19 know, Mr. Barreto, is in August of 2018,
20 Teva has information about NDEA, we saw
21 that in the Icelandic response; other
22 agencies are mentioning or asking about
23 NDEA; why didn't Teva just say, jeez,
24 Mylan, I'm hearing a lot about NDEA, go

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1 test for that and tell us a justification
2 for that, too?
3 Did anyone do that?
4 MS. LOCKARD: Object to
5 form. Compound. Argumentative.
6 THE WITNESS: My -- my --
7 based on the experience with this
8 process, my conclusion was that at
9 that time, based on that knowledge
10 that we had -- and, I think, based
11 also on the fact that, you know,
12 there had been a regulatory
13 authority which had tested
14 product, that we, at that point in
15 time, we did not see the need to
16 do a follow-up, if we didn't do a
17 follow-up.
18 BY MR. STANOCH:
19 Q. It turned out, ultimately,
20 that there was NDEA in Mylan's valsartan
21 API, right?
22 A. That is correct.
23 Q. And, in fact, it was in
24 pretty high concentrations; do you recall

Page 310

1 that?

2 A. Yes.

3 Q. And, in fact, there's some

4 reference in the documents to, you know,

5 five times the .08 limit that was

6 ultimately set.

7 Do you recall that?

8 A. I believe you're correct.

9 Q. Why did Mylan's recall of

10 product with Mylan API not become

11 effective until November 13th, 2018, if

12 it was aware of it, at the very latest,

13 on November 5th, 2018, as it told the

14 FDA?

15 A. There was an investigation

16 that was performed. We were in contact

17 with the FDA, and we were in discussions

18 with the FDA.

19 This was, again, one of

20 those where we needed to make sure that

21 we had all the information that was

22 needed. The FDA also continued to have a

23 concern with respect to supply to

24 patients.

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1 So, again, this is not a

2 normal situation where, you know, you

3 just do a normal recall of product and

4 then you move on. So the situation was

5 as complex as it could be, so we had to

6 work with the agency. And there were

7 different communications with them.

8 Q. And you mentioned this in

9 the morning, Teva undertook to do a

10 for-cause audit of ZHP following the news

11 about the nitrosamine impurities, right?

12 A. That is correct.

13 Q. And that audit occurred

14 eventually in the fall of 2018?

15 A. I think so.

16 Q. And then did Teva ever do a

17 for-cause audit of Mylan?

18 A. I think so.

19 Q. Do you know when that

20 occurred?

21 A. I would have to check. I

22 don't remember right now the exact date.

23 Q. And I can put a document in

24 front of you, but, you know, does July

Page 312

1 2019 sound right?

2 A. I'm not sure. I would have

3 to check.

4 Q. Okay. I'll pull out the

5 document.

6 But I guess the question is

7 going to be, sir, is that Teva knew about

8 the potentiality of NDEA contamination as

9 early as August 2018, and then told the

10 FDA about it in November of 2018; why did

11 it take so long, almost, you know, nine

12 months or so, for Teva to conduct an

13 audit of Mylan?

14 A. We were in discussions with

15 Mylan in terms of looking for a way to

16 reach out to them to do that audit. So

17 we were in constant communication with

18 them.

19 Sometimes you're able to get

20 an audit when the API supplier is

21 available and ready. They were

22 conducting their own investigations, and

23 they were consistently asking us for the

24 opportunity for them to continue to

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1 perform those investigations, and then

2 for the right time to be chosen when to

3 do a follow-up.

4 Q. It wasn't just that, they

5 were -- Mylan was actively refusing to

6 let Teva come do an audit; wasn't that

7 right?

8 A. I do not necessarily agree

9 with that. I mean, we were in constant

10 communication with them. The situation

11 was an extremely complex situation.

12 So they -- we knew, based on

13 also what we were experiencing, that we

14 needed to complete a certain number of

15 tasks responding to different regulatory

16 organizations.

17 So it was just a matter of

18 being able to find the right opportunity

19 and the right priority to conduct the

20 audit.

21 Q. And the right priority or

22 opportunity was what, nine, ten months

23 after the NDEA was disclosed?

24 MS. LOCKARD: Objection.

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1 Argumentative.
2 THE WITNESS: The purpose of
3 the audit, from my perspective, in
4 terms of the timing -- for us,
5 what was important was to receive
6 the information from them. We
7 received investigation reports
8 from them.
9 So while we had not
10 conducted a true physical audit of
11 the facility, we had sufficient
12 information from them to assess
13 the situation.
14 We did perform a recall. We
15 did not continue to sell product
16 in the United States, because
17 there was no product to sell. So
18 in terms of risk to the market,
19 risk to patients, there was a
20 continuing action in that regard.
21 So for us -- you know, what
22 was really important for us was to
23 make sure that, at the point at
24 which Mylan was going to be able

Page 315

1 to demonstrate that it had
2 implemented the right level of
3 corrective actions, that we would
4 be in a good position to actually
5 perform that audit.
6 BY MR. STANOCH:
7 Q. Teva has procedures in
8 place, does it not, for how it is
9 supposed to conduct audits?
10 A. Of course.
11 Q. Right. And that includes
12 both periodic as well as for-cause
13 audits, correct?
14 A. That is correct.
15 Q. And isn't it your
16 understanding that for-cause audits are
17 supposed to happen promptly, not nine,
18 ten, eleven months after the fact?
19 A. The purpose of that is to
20 schedule those as promptly as we can.
21 And, obviously, in order to be able to do
22 that, we are dependent on the
23 availability of the API supplier to host
24 that audit.

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1 So for the most part, these
2 different conditions actually define the
3 extent to which we're able to fulfill
4 that expectation, which is dependent on
5 an external party to also support the
6 expectations of the policy.
7 Q. That external party, in this
8 instance, is one of Teva's vendors,
9 correct?
10 A. That is correct.
11 Q. So Teva was at the mercy of
12 its vendor to deem it okay for Teva to
13 come and conduct an on-site for-cause
14 audit concerning a global nitrosamine
15 impurity issue?
16 A. I would not characterize it
17 that way. And the reason for that is the
18 objective of the audit, in this case,
19 would have been to further assess the
20 extent to which corrective actions had
21 been implemented.
22 While the company -- the
23 vendor is engaging those corrective
24 actions, the objectives of the audit

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1 would not necessarily be met. So I'd
2 rather have my auditors go to a site that
3 has spent whatever amount of time it has
4 needed to do whatever corrective actions
5 they need to do before I can then go
6 there, do an assessment of the corrective
7 actions, and then come back to Teva and
8 say, they have implemented corrective
9 actions, we are able now to receive
10 product; or, no, they have not fulfilled
11 our expectations, and I propose that we
12 do not purchase product until the
13 correct -- the corrective actions are
14 effectively implemented.
15 Q. Do you think it was
16 reasonable for Teva to wait until July
17 2019 to conduct the on-site for-cause
18 audit of Mylan in connection with the
19 nitrosamine issues?
20 A. In this case, it is not
21 about, in my perspective, an issue of
22 reasonable. It's more an issue of the
23 timing.
24 Obviously, as they explained

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1 to us what they were doing and the reason
2 why they couldn't host the audit, it was
3 clear to us that the benefit of
4 conducting the audit would be better
5 served at the point at which they had
6 implemented corrective actions.
7 Q. Mr. Barreto, I hear that.
8 But given the circumstances,
9 how can you trust Mylan, given the
10 sequence of events here?
11 A. We received the information
12 that we needed to receive from them
13 through investigations, analytical data,
14 and we used that information to
15 effectively implement the most important
16 corrective action on our part, meaning
17 the removal of product from the market.
18 We are not making -- after
19 that, we were not receiving any materials
20 from them. So attending -- or performing
21 an audit would not necessarily be a
22 value-added activity from my perspective.
23 Q. Because Mylan told Teva in
24 August 2018 that there's no NDMA and that

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1 turned out to be wrong, right?
2 A. Are we talking about NDEA?
3 Q. Well, in August 2018, they
4 said there's no way NDMA --
5 A. That's right.
6 Q. -- could form at all, right?
7 And that turned out to be wrong to some
8 extent, correct?
9 A. And the assessment that they
10 performed at that point in time fulfilled
11 our expectations.
12 And as I said to you, we
13 also had analytical data from a reliable
14 regulatory body that had indicated that
15 the product was free from -- from this
16 impurity.
17 So for us -- you know, we
18 have to rely on regulatory bodies and the
19 work that they do. And to us, there was
20 no reason not to rely on the assessment
21 that Swissmedic did of the products from
22 Mylan at the time.
23 Q. Right. And you can rely on
24 other regulatory bodies, be it Iceland or

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1 Malta or Hong Kong, or a host of others,
2 that were contacting Teva simultaneously
3 saying that there's issues of potential
4 NDEA contamination, right?
5 A. And we did. And we did not
6 ignore that. And we continued to pursue
7 our investigations.
8 And if I'm not mistaken, you
9 know, we continued to revise our
10 questionnaires. We set a strategy for
11 ensuring that when we went back to the
12 API suppliers that they would respond to
13 specific questions with respect to not
14 only the NDMA but any other potential
15 impurities. So we did -- we were
16 actually applying the learnings of this
17 unexpected experience.
18 Q. That was well after -- this
19 questionnaire issue, this was after
20 November 2018 that any of that started to
21 happen; isn't that right?
22 A. It is correct.
23 Q. Right. There's nothing
24 between June 28th, 2018, and November

Page 321

1 5th, 2018, that you're aware of, where
2 Teva was asking Mylan to do any testing
3 of its valsartan API, for example?
4 A. Again, there was no reason
5 for us to -- to, let's say, question
6 Mylan's certification to us at the time.
7 There was no -- there was no reason for
8 that.
9 Q. The only certification you
10 had was about NDMA, right?
11 A. Correct.
12 Q. You didn't have any
13 certification from Mylan about NDEA, did
14 you?
15 A. No.
16 And I think it's important
17 to make a distinction here. You know,
18 we -- we asked Mylan about NDMA because
19 we were interested in the manufacturing
20 process being a contributor to the
21 presence of impurities.
22 When you look at the NDEA
23 issue, it's a separate discussion.
24 Q. The regulators that you keep

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1 mentioning, they talked about all
2 nitrosamines impurities together, didn't
3 they? Right.
4 So it's not a completely
5 separate issue, right? That's really --
6 that's a little extreme; would you say
7 that's fair?
8 A. Yeah. But what I'm saying,
9 counsel, is that, you know, everything
10 started with NDMA and then followed by
11 NDEA. And if the story continued, there
12 were actually other impurities that would
13 pop up.
14 So we learned as we went.
15 That's true for us in the industry.
16 That's true for the suppliers. That's
17 true for the regulators.
18 Q. And then shortly after Teva
19 was informed by Swissmedic of the NDEA on
20 November 5th, 2018, Teva went ahead and
21 had some Mylan valsartan API tested for
22 NDEA; isn't that right?
23 A. I think so.
24 Q. And it had those results

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1 within a week, I think; isn't that right?
2 A. Those results were from
3 Mylan, if I'm not mistaken.
4 Q. The Mylan test results were
5 within a week; is that right?
6 A. I think so.
7 Q. And Mylan's test results
8 showed that 9 out of 10 batches tested
9 above the specification of 0.8 part per
10 million for NDEA, correct?
11 A. Correct.
12 Q. So once Teva told the FDA
13 about NDEA in Mylan API on November 8th
14 of 2018, less than a week later, Mylan
15 actually gets a test and sends test
16 results and shows NDEA in the API, right?
17 A. Well, we -- part of the
18 communication that we had with Mylan, we
19 were asking them to produce test results
20 for us. So they -- they're in possession
21 of all their APIs, they're in possession
22 of the information.
23 So it's part of the process
24 where, you know, they had indicated to us

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1 that they were working on doing the
2 testing activities that were required.
3 Q. Right. And less than a week
4 after Teva made that request, they had in
5 hand, from Mylan, valsartan API test
6 results showing 9 out of 10 batches with
7 above-specification NDEA impurity
8 results, right?
9 A. That's correct.
10 Q. So, I mean, there's no
11 reason to think that if Teva simply
12 picked up the phone and made that request
13 back in August 2018 it would have had
14 those same results months earlier; isn't
15 that fair?
16 MS. LOCKARD: Objection.
17 Calls for speculation.
18 THE WITNESS: Yeah, I don't
19 recall. But I know that as soon
20 as we became aware of a potential
21 for NDEA, we immediately requested
22 Mylan to start the process of
23 testing product, which is part of
24 the commitment they also made.

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1 BY MR. STANOCH:
2 Q. What was the date of that
3 request from Teva to Mylan?
4 A. I'd have to -- I'd have
5 to -- I want to say it was immediately
6 after we were notified, but I have to
7 look at the date.
8 Q. Immediately after you were
9 notified by Swissmedic on November 5th,
10 2018?
11 A. Correct.
12 Q. That's fair.
13 I'm just -- are you aware of
14 anything that would have prevented Teva
15 from asking Mylan, back in August 2018,
16 for NDEA test results for the valsartan
17 API?
18 A. I don't think so.
19 Q. And, in fact, if we had a
20 quality agreement between Mylan and Teva,
21 there might have been a provision, you
22 know, governing such a request, but we
23 don't know because we don't have that
24 agreement; is that right?

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1 A. Not necessarily. I mean,
2 this is a very unique situation. So I
3 think that the conditions were correct,
4 in place for -- as soon as we had the
5 information, we were able to communicate
6 the need for them to conduct the testing,
7 and they did.

8 Q. Right. And Teva waited for
9 someone else to tell them that NDEA was
10 found before Teva did the testing itself
11 or asked Mylan to do the testing?

12 A. So because of the lack of
13 the analytical test methods on our part
14 and the number of APIs that we were
15 looking at, we definitely put that
16 first -- first responsibility for
17 providing the test results on the API
18 suppliers so that we could then use that
19 information to make decisions.

20 Q. Right. And Teva didn't ask
21 for that until on or after November 5th,
22 2018, from Mylan?

23 A. I do not think that -- as I
24 said, I'm sure that we asked Mylan to

Page 327

1 give us test results as soon as we became
2 aware that there was a potential NDEA
3 issue with valsartan for Mylan.

4 Q. Right. And we went over
5 this.

6 All I'm saying is Swissmedic
7 informed Teva about NDEA on November 5th,
8 2018, right? We saw that.

9 A. Yes.

10 Q. And then you're saying that
11 Teva asked Mylan for the test results
12 after it was informed.

13 So it must have been after
14 that November 5th, 2018, date, right?

15 A. Yes. Immediately after,
16 yes.

17 Q. That -- are you familiar
18 with the reduced testing, sir?

19 A. Yes.

20 Q. What's your understanding of
21 reduced testing as it relates to incoming
22 valsartan API that Teva would be
23 purchasing?

24 A. So reduced testing is a

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1 process whereby, after you have
2 established a certain level of
3 reliability of the quality of the
4 supplies that you receive, then you are
5 in a position to do testing at a lower
6 level of, let's say, oversight, based on
7 that historical performance of the API,
8 the quality of the API.

9 Q. And is it your understanding
10 that Teva Jerusalem had the Mylan
11 valsartan API on a reduced testing
12 program?

13 A. It may have indicated that.
14 I would have to double check that.

15 MR. STANOCH: I'll mark
16 Exhibit-153. Bates ending 415117.
17 - - -
18 (Whereupon, Exhibit
19 Teva-153, TEVA-MDL2875-00415117,
20 Site Risk Assessment Protocol, was
21 marked for identification.)
22 - - -
23 BY MR. STANOCH: ^^
24 Q. Tell me when you have it,

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1 sir.

2 A. Yes.

3 Q. This appears to be a site
4 risk assessment protocol prepared by Teva
5 Jerusalem?

6 A. Yes.

7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 Can I read it, please?

20 Q. Sure.

21 A. My apologies, I'm looking at
22 this thing sideways. My apologies,
23 counsel.
24 - - -

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1 (Whereupon, a discussion off
2 the record occurred.)
3 - - -
4 BY MR. STANOCH:
5 Q. I understand you're trying
6 to rotate the document on your screen.
7 We can wait. That's fine.
8 A. Thank you. Let me look at
9 it sideways. That's okay.
10 - - -
11 (Whereupon, a discussion off
12 the record occurred.)
13 - - -
14 VIDEO TECHNICIAN: The time
15 is 2:58 p.m. Going off the
16 record.
17 - - -
18 (Whereupon, a brief recess
19 was taken.)
20 - - -
21 VIDEO TECHNICIAN: The time
22 is now 3:08 p.m. Back on the
23 record.
24 BY MR. STANOCH:

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1 Q. Mr. Barreto, before the
2 break for technical reasons, we were
3 looking at the exhibit ending 415117. It
4 was the site risk assessment protocol for
5 the Teva Jerusalem facility.
6 Do you recall that?
7 A. Yes.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 A. That appears to be the case.
2 Q. In fact, I see -- we'll
3 leave it at that. Okay.
4 And you're not personally
5 familiar with the actual analytical
6 testing done at facilities, such as Teva
7 Jerusalem, of incoming API, are you?
8 A. You mean in terms of the
9 general expectations I have, the
10 specifics I am not.
11 Q. Right.
12 MR. STANOCH: The specifics,
13 counsel, I assume that might be
14 better for Mr. Binsol perhaps.
15 MS. LOCKARD: That's the
16 expectation.
17 MR. STANOCH: Great. Just
18 want to be on the same page.
19 BY MR. STANOCH:
20 Q. Eventually, sir, you'll
21 recall that Teva did audit, finally,
22 Mylan's Unit 8 in 2019?
23 A. I think so.
24 Q. Right. And do you recall

Page 333

1 the result that -- of that audit?
2 A. I don't recall the
3 specifics. But I think some
4 recommendations may have been made. I
5 would have to look at that report again.
6 Q. Okay. I'll put it in front
7 of you.
8 But, ultimately, did Teva's
9 audit in July 2019 find Mylan's Unit 8 to
10 be acceptable?
11 A. Yes, correct. That's
12 correct.
13 Q. That meant, as far as Teva
14 was concerned, Mylan had no major GMP
15 deviations and Teva could source product
16 from that Mylan facility, right?
17 A. Correct.
18 Q. I mean, are you aware that
19 the FDA issued a Form 483 to that very
20 same Mylan facility, Unit 8, later that
21 year?
22 A. Yes.
23 Q. And then in November of
24 2019 -- does that sound right to you?

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1 A. I think so.
2 Q. And then, in fact, the FDA
3 found significant deviations from current
4 good manufacturing practices for active
5 pharmaceutical ingredients at Mylan's
6 Unit 8.
7 Do you recall that?
8 A. Yes.
9 Q. So Teva's audit went in and
10 said, Mylan Unit 8 is acceptable, but
11 then the FDA found significant deviations
12 of current good manufacturing practices
13 for active pharmaceutical ingredients; is
14 that right?
15 A. That is -- that is correct.
16 But that's not completely unusual, and it
17 can happen both ways.
18 Q. And Teva would defer to the
19 FDA's findings concerning deviations from
20 good manufacturing practices at vendors
21 that Teva is sourcing material from?
22 A. What's the question?
23 Q. Teva would defer to the
24 FDA's findings of significant deviations

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1 of current good manufacturing practices
2 at vendors from whom Teva is sourcing
3 API; is that fair?
4 A. Teva would use information
5 from FDA inspections to actually do a
6 further assessment through the GMP
7 process.
8 Q. Were you aware of any
9 sentiment at Teva to speed along Mylan's
10 Unit 8 being considered acceptable again
11 so Teva could start buying product from
12 it again?
13 MS. LOCKARD: Objection.
14 Vague.
15 THE WITNESS: The objective
16 of the audit that we performed for
17 Mylan was intended to establish
18 the extent to which we would be in
19 a position to accept or not the
20 product manufactured by Mylan.
21 Expediency in this case, and
22 in every case, but especially in
23 this one, because of the
24 seriousness of what the findings

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1 of impurities in valsartan, was
2 not a consideration.
3 It's not in the best
4 interest of Teva to purchase
5 materials that -- that would not
6 be considered to be acceptable and
7 then produce them into finished
8 product and then find itself
9 having to engage in a recall and
10 affecting, you know, the
11 credibility of the company as a
12 reputable company.
13 Expediency is not what we
14 want.
15 BY MR. STANOCH:
16 Q. Did Teva change its prior
17 acceptable classification from Mylan's
18 Unit 8 after it became aware of the FDA's
19 Form 483 for that Mylan facility in
20 November of 2019?
21 A. I would have to look into
22 exactly what we did.
23 But I can tell you that we
24 looked into those observations issued by

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1 the FDA, and we did an assessment.
2 Q. And I don't have it in front
3 of me, can you remind me of when you
4 departed from Teva?
5 A. I left Teva in January 2020.
6 Q. And I'm looking at
7 information from November 2019 concerning
8 the FDA's warning letter on Mylan Unit 8.
9 That was shortly before,
10 then, that you were going to depart from
11 Teva?
12 A. That's correct.
13 Q. And who, if anyone, assumed
14 responsibilities you had vis-à-vis
15 follow-up audits or inquires of API
16 suppliers such as Mylan?
17 A. You mean after my departure?
18 Q. Yes, sir.
19 A. In -- I know there was a
20 reorganization. So at that time there
21 was some transition, so I could not
22 exactly tell you who was going to take
23 those responsibilities.
24 It could have been Mr.

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1 Delicato, but I don't know.
2 Q. Are you aware of any
3 assessment at Teva as to whether Teva's
4 audit of Mylan in July 2019 found the
5 same deviations or not as the FDA's?
6 A. I don't recall. I don't
7 think so.
8 Q. Do you think it's possible
9 that Teva's audit of Mylan in July 2019
10 missed the same significant deviations
11 that the FDA caught and reflected in its
12 warning letter about Mylan's Unit 8?
13 A. What I think happened is,
14 because you're asking me for my opinion,
15 based on my experience as an auditor and
16 a former FDA investigator, FDA
17 investigators are looking at certain
18 things in the course of their
19 inspection -- and this will also vary
20 from one investigator to another.
21 So the Teva audit also had
22 its own purpose and objective. So you
23 will have instances where the findings
24 found -- reported by the FDA, it's not

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1 that the auditor did not find them, it's
2 that probably the auditor was looking at
3 other activities and other specific
4 issues.
5 In our case, I know that we
6 were interested in the manufacturing
7 process from a nitrosamine perspective.
8 So it was a focused audit.
9 So I think that it's just
10 different approaches that would yield
11 different results.
12 Q. Right. Teva's audit was
13 focused on the manufacture of valsartan
14 and other sartan API in light of the
15 nitrosamine issues, right?
16 A. That's correct.
17 Q. The FDA's inspection, at
18 least from what it said in its warning
19 letter, was about the manufacture,
20 testing and handling of active
21 pharmaceutical ingredients; you're aware
22 of that?
23 A. Yes. And that may or may
24 not have included just the sartans.

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1 But, again, the approach and
2 the focus from one auditor to another
3 will vary depending on their level of
4 skills and capabilities.
5 Q. And you, obviously, sitting
6 here today, can't say, one way or the
7 other, what it is that caused the FDA to
8 find significant deviations in current
9 good manufacturing practices for active
10 pharmaceutical ingredients at Mylan's
11 Unit 8 and -- whereas Teva's audit did
12 not?
13 A. No, I couldn't tell you.
14 Again, because it's very difficult to
15 predict or to analyze why certain things
16 are found in -- by one auditor and not by
17 another.
18 Q. Did Teva cease sourcing
19 product from Mylan's Unit 8 after it
20 became aware of the FDA warning letter in
21 November of 2019?
22 A. I would have to check,
23 because that may have been a decision
24 that was done, perhaps, after my -- when

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1 you say stopped, it could have been
2 permanent? You mean a permanent stop?
3 Q. Any stop.
4 A. I'd have to check. I
5 apologize.
6 Q. No. That's fine.
7 And that's actually a good
8 lead to a broader question.
9 In your role as a quality
10 executive at Teva, would the company --
11 what was the effect of a Teva audit
12 finding an API supplier acceptable or not
13 acceptable?
14 A. So what's the question? Is
15 this a general question?
16 Q. General question. Yes.
17 A. Okay. So what -- how do we
18 get to acceptable versus not acceptable?
19 Q. No. I was unclear.
20 So in the event auditors
21 under you find a site, let's say,
22 unacceptable, any site generally, what is
23 the effect on Teva at large's purchasing
24 or not from that supplier?

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1 So even if you find someone
2 not acceptable, can Teva still say, on
3 the business side, we're still going to
4 purchase?
5 A. So the whole objective of
6 unacceptable, it would have to --
7 different -- actually, different
8 potential outcomes.
9 If the unacceptability is
10 based on impact on product quality
11 because, you know, the way in which the
12 product is manufactured would have a
13 significance, so we would not purchase.
14 If the unacceptability has
15 other ramifications like, you know, they
16 don't necessarily have, let's say, strong
17 quality organization or a strong
18 manufacturing organization or we think
19 that, you know, the equipment that they
20 use is not up -- there would be a number
21 of potential reasons for unacceptability,
22 then we would have to make a risk-based
23 decision as to whether or not, you know,
24 that unacceptable is conclusively

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1 recommending that we don't purchase
2 product from that company.
3 Q. And where does that ultimate
4 decision, within Teva, lie?
5 A. The decision itself?
6 Q. Yes.
7 So, again, I'll give you an
8 example. A Teva audit results in a
9 finding of unacceptable for whatever
10 reason. That's presented to someone.
11 Who is that someone to make
12 that decision whether they're going to
13 stop purchasing or not?
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

Page 345

7 Q. Are you aware of whether
8 Teva had ever audited any of Mylan's
9 suppliers of any materials used to make
10 valsartan API?
11 A. I'm trying to remember now
12 if Mylan acquired an intermediate from
13 ZHP, for instance. I don't know. I
14 would have to further follow up.
15 Q. And I -- let me back up.
16 I can put Teva audit reports
17 in front of you from 2015 and 2018, if
18 you'd like, I'm happy to do that, but,
19 you know, sitting here today, do you
20 recollect now, or even in your role as a
21 quality executive at Teva, whether Teva
22 ever audited any of the raw material
23 suppliers to Mylan for valsartan API?
24 A. I don't -- I don't recall

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1 seeing any of those activities done.
2 Q. Do you --
3 A. This would be -- the only
4 way that I think we would do that is if
5 there was a for-cost issue on our part.
6 And even at that point, I think that
7 our -- my expectation would be for us to
8 tell Mylan to perform its own audit of
9 that supplier and for them to give us a
10 report.
11 Q. Fair enough.
12 Are you aware of Teva ever
13 informing Mylan that Mylan should conduct
14 an audit of one of its raw material
15 suppliers in connection with the
16 manufacture of valsartan API?
17 A. I'm not aware.
18 Q. Are you aware of Mylan ever
19 sharing any audit of Mylan's API raw
20 material suppliers with Teva?
21 A. I'm not aware.
22 Q. Are you aware of any
23 communications between Teva and Mylan
24 concerning solvents that Mylan used to

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1 make valsartan API from Lantech?
2 A. I am not aware.
3 Q. Are you aware of Teva ever
4 conducting any investigation or audit
5 itself of Lantech concerning the solvents
6 that it used to manufacture any valsartan
7 API?
8 A. I'm not aware.
9 Q. Are you aware of -- is Teva
10 aware of any information that Mylan ever
11 investigated Lantech's processes for
12 using solvents that are part of the
13 valsartan API manufacturing process?
14 A. I'm not aware.
15 Q. Are you aware of whether any
16 of Teva's audits of Mylan evaluated
17 whether the o-xylene solvent that Mylan
18 was using to make valsartan API sold to
19 Teva was recycled or not?
20 A. I'm not aware of that
21 happening.
22 Again, something like that,
23 the fact that recycled o-xylene was used
24 would not necessarily trigger any sort of

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1 further investigation on the part of the
2 auditor in detail.
3 Q. And you're not aware of
4 Mylan ever making Teva aware that it was
5 using recovered o-xylene solvent in the
6 manufacture of valsartan API sold to
7 Teva?
8 A. I'm not aware of that. But
9 I would not necessarily expect them to do
10 that unless they had a good reason for
11 it.
12 Q. Would you expect Mylan's DMF
13 for valsartan API to disclose whether the
14 o-xylene used was fresh or recycled?
15 A. Again, not necessarily. I
16 mean, the use of recovered solvents, it's
17 a common practice within the industry.
18 So if Mylan was receiving --
19 or using recovered solvents and those
20 solvents were fulfilling their quality
21 expectations, if they report those to the
22 DMF or not, that would not necessarily be
23 a high issue of concern on my part.
24 Q. But either way, it's

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1 something that you're not aware of Teva
2 ever being aware of?
3 A. That is correct.
4 Q. Were you aware of whether or
5 not Teva had a vendor qualification
6 policy while you were employed there?
7 A. I'm sure we do have a vendor
8 qualification policy, yes.
9 Q. Do you recall whether there
10 were any concerns about Teva facilities'
11 differing interpretations of that policy?
12 A. I'm sorry, can you ask the
13 question again?
14 Q. Sure.
15 Were you aware of any
16 concerns about different Teva facilities
17 having different interpretations of
18 Teva's vendor qualification policy?
19 A. No, I'm not aware of any
20 concerns.
21 MR. STANOCH: I'll mark the
22 next exhibit.
23 THE WITNESS: You're going
24 to upload another document,

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1 counsel?
2 MR. STANOCH: I am. Sorry,
3 stand by. Teva Exhibit-154.
4 Bates ending 132980.
5 - - -
6 (Whereupon, Exhibit
7 Teva-154, TEVA-MDL2875-00132980,
8 10/2/17 E-mail, McClain to
9 Barreto, was marked for
10 identification.)
11 - - -
12 BY MR. STANOCH:
13 Q. Tell me when you have it in
14 front of you, sir.
15 A. I do have it.
16 Q. And this appears to be an
17 e-mail from a Lorraine McClain,
18 October --
19 A. Yes.
20 Q. -- 2, 2017, to you and
21 others?
22 A. Yes.
23 Q. And it's attaching the Teva
24 vendor qualification policy, Corp Policy

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1 0082, yes?
2 A. Yes.
3 Q. And the policy that's
4 attached is effective August 26th, 2017?
5 A. Yes.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 Q. And there's -- on the cover
15 e-mail of Ms. McClain -- actually, who is
16 Ms. McClain? Do you recall?
17 A. Yes, of course. She was
18 actually the vendor qualification program
19 manager from the quality organization.
20 She left the company, I want to say,
21 sometime before -- was it before the end
22 of 2017? I don't remember now. But she
23 is no longer with the organization.
24 [REDACTED]

Page 352

[REDACTED]

Page 353

[REDACTED]

Page 354

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
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16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Q. How was a facility purchasing, say, API from a vendor supposed to know what it was supposed to do if a requirement was classified as a case-by-case basis?

A. Again, I don't know exactly what was stated -- what was meant with the case-by-case basis. So it's a little vague for me to actually really give you a very good perspective on this.

Q. Go ahead.

A. The only thing -- the only thing that I can tell you is that the vendor qualification program, it's a very extensive program. And vendor

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1 qualification includes a number of
2 activities that are, you know, core.
3 One is the identification of
4 the vendor, the assessment of the vendor
5 capabilities to deliver product, even
6 their financial status, location,
7 geographical location, the type of
8 organization, building facilities.
9 And then, of course, when it
10 comes to product is whether or not
11 they're able to manufacture product
12 according to our specifications.
13 So I'm trying to
14 understand -- you know, there may have
15 been concerns from the sites, in terms of
16 clarity, which is normal, in terms of
17 what the document says.
18 But in terms of the
19 expectation that each site is supposed to
20 have for vendor qualification, that's
21 pretty clear, what -- you know, it's
22 pretty standard.
23 Q. I'm going to share my screen
24 so you can follow along a little bit,

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1 sir, one moment.
2 A. Okay. Please do. Let me --
3 Q. Sorry. One second.
4 Can you see that?
5 A. Yes.
6 Q. It's a flow chart,
7 Attachment 1.
8 It's in the same document
9 you have, it's just towards the end of
10 the policy, right?
11 A. Uh-huh.
12 Q. And if you go to the next
13 page, there's Attachment 2, it's, Vendor
14 qualification requirements per
15 material/service provider type.
16 Do you see that?
17 A. Yes, I do.
18 Q. And you'll see there's a
19 variety of requirements, vendor
20 questionnaire, declaration, drug master
21 file, et cetera.
22 Do you see those?
23 A. Yes.
24 Q. And then there are, I guess,

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1 the type of vendor, API, excipient,
2 intermediate, packaging, right?
3 A. Yes, correct.
4 Q. And then there's a code, a
5 letter in the chart, which is usually an
6 M or a C.
7 A. I see what you're saying,
8 yes.
9 Q. And this seems to suggest
10 that when something is a C, it's a
11 consider on a case-by-case basis, which
12 is being referred to in the cover e-mail;
13 is that fair?
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 358

1 [REDACTED]
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22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 Q. At the time you were at
18 Teva, were you aware of any written
19 guidelines or guidance that would have
20 helped Teva facilities understand how to
21 interpret or implement something
22 classified here in this policy as C,
23 consider on a case-by-case basis?
24 A. I don't recall seeing one.

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1 But, again, as I said, I
2 mean, I'm looking at it, and it's pretty
3 straightforward to me. I'm hoping that
4 that will be the case for most
5 professionals within the organization.
6 And if it's not, then we
7 will provide clarification.
8 Q. Do you recall ever providing
9 clarification, while you were at Teva,
10 concerning this policy?
11 A. I'd have to look at the next
12 version. But, again, this was delegated
13 on Ms. McClain. So I don't recall if I
14 looked at the specifics at that point.
15 Q. While we're on this, for
16 vendor-supplied API, a quality technical
17 agreement was mandatory, right?
18 A. That is correct.
19 MS. LOCKARD: Objection.
20 Asked and answered.
21 BY MR. STANOCH:
22 Q. And then I think you said
23 test method and validation was -- is
24 classified as C, consider on a

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1 case-by-case basis?
2 A. And the reason for that was
3 in the event of a USB method, you don't
4 validate that test method, you verify it.
5 Q. Eventually, at some point,
6 Teva did test or -- strike that.
7 Teva did validate a method
8 for testing nitrosamines, correct?
9 A. That's my understanding. I
10 think Mr. Binsol will give you much
11 better details as to the answer to that.
12 Q. And, ultimately, the results
13 of the testing were reduced to a testing
14 report that was shared with the FDA?
15 A. I think that happened after
16 my departure, so I would defer to Mr.
17 Binsol to give you those details.
18 Q. Do you recall whether the
19 FDA shared any of its own test results
20 with Teva?
21 A. Yes, they did.
22 Q. All right. And Teva --
23 strike that.
24 FDA did test some of Teva's

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1 U.S. finished-dose valsartan, right?
2 A. Yes. They asked for
3 samples, and we supplied those samples to
4 them.

5 Q. Right. And the FDA's
6 testing of the Teva finished dose in the
7 U.S. market, it found NDMA in excess of
8 .3 parts per million, correct?

⁹ A. I think that was the case.

10 Q. And do you recall that
11 Teva's own testing of valsartan API from
12 ZHP confirmed the presence of NDMA,
13 right?

14 A. I'm trying to remember if
15 that happened prior to or after my
16 departure. Because I know that that was
17 a long discussion in terms of how -- I'm
18 trying to remember if that was our
19 testing or if it was just testing by
20 others.

21 Q. And it was both, I think, in
22 that -- in that ZHP did its own testing
23 and then Teva did some of its own testing
24 as well.

¹ iterations of this. This one is, there
² are attachments to an e-mail from
³ February 15th, 2019.

⁴ Do you see that e-mail?

5 A. It's uploading, just a
6 couple of seconds.

⁷ Q. Sure.

⁸ A. I'm looking at it, yes.

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¹ Do you recall that?

2 A. Oh. Oh, because we were --
3 I think we were using an external testing
4 laboratory at one point to do some
5 testing for us. I remember that now.

6 Q. Do you recall roughly when
7 that was?

A. I want to say somewhere
between September or October 2018.

10 Q. And I can put it in front of
11 you, but -- I'll put it in front of you,
12 give me one second, sir. Stand by.

13 A. Okay. You're speaking --
14 okay.

15 Q. Teva-155, sir.

16 - - -

(Whereupon, Exhibit
Teva-155,
TEVA-MDL2875-00546489-6492,
2/15/19 E-mail, Lyons to Gray, was
marked for identification.)

22 _ _ _

23 BY MR. STANOCH:

24 Q. And there's various

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1 again. I'm happy to do that to move it
2 along.
3 A. Allow me a second, and I'll
4 let you know, counsel.
5 Q. Sure. I appreciate your
6 flexibility.
7 A. Thank you. I appreciate
8 that. Counsel, do you mind sharing the
9 document with us?
10 Q. No, that's fine. I'll do
11 that right now, sir.
12 This was just -- we were
13 just looking at -- here is the e-mail.
14 Do you see it?
15 A. Yes. Yes, sir.
16 Q. And then we were looking at
17 the Dupnitsa results, right?
18 A. That is correct.

■ [REDACTED]

Page 367

■ [REDACTED]

Page 368

■ [REDACTED]

Page 369

■ [REDACTED]

Page 370

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 Q. Great. If you want to tell
20 me something about it, feel free, but I'm
21 happy to put the target on Mr. Binsol's
22 back for that one.
23 A. I think -- I think Mr.
24 Binsol is more than prepared to assist

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1 you.
2 Q. I'm sure. Thank you.
3 You're aware that Teva had
4 conducted an on-site audit of ZHP shortly
5 before the news about the NDMA impurity
6 in 2018, right?
7 A. I think so, yes.
8 Q. And I think that was
9 conducted in late May, I believe.
10 Does that sound right?
11 A. That may be right, yes.
12 Q. And I can put the audit
13 report in front of you when we get to it,
14 but did you have any personal involvement
15 in that audit of ZHP?
16 A. As part of my
17 responsibility, I have always had
18 interest in the audits performed by the
19 organization. It was all part of an
20 objective of myself to look into how
21 audits were performed, because of my
22 responsibility, and whether or not the
23 auditors were either, you know, focusing
24 on the areas that they needed to focus

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1 on, from my perspective, or that the
2 reports that were generated, you know,
3 clearly described their findings and
4 their concerns and the extent to which,
5 you know, the client was responding to
6 the observations, that sort of thing.
7 So I did have a very
8 personal interest in a number of these
9 audits. Definitely, yes.
10 Q. I appreciate that as your
11 general view or approach to your
12 responsibilities.
13 But specifically concerning
14 the audit of ZHP in May of 2018 --
15 A. I may have. I may have.
16 Q. Do you recall -- let's take
17 it step by step.
18 You didn't join the audit
19 team at ZHP's facility in May 2018,
20 correct?
21 A. No, I did not.
22 Q. And do you recall reviewing
23 drafts of the report, before it was
24 finalized, after the inspection?

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1 A. I may have. Because, again,
2 I had an interest in looking at a number
3 of reports to see if they reflected, you
4 know, the expectation that I had for the
5 quality of the report.
6 Q. And sitting here today,
7 you're not sure, one way or the other,
8 whether you reviewed the May 2018 audit
9 report for ZHP?
10 A. I don't recall. But being
11 an API supplier -- I would not look at a
12 packaging, you know, facility, you know,
13 or a small, you know, processing of a
14 less significant product.
15 But the reason why I say I
16 may have is because I'm sure that -- and
17 I had three regions that I was
18 responsible for. So I wanted to make
19 sure that I also looked at the activities
20 from each one of the regions to see if we
21 were even establishing some form of, you
22 know, standardization, harmonization in
23 our practice and approach.
24 Q. And, in fact, Teva had also,

<p>Page 374</p> <p>1 I think, audited Mylan in 2018, prior to 2 June 2018 and the NDMA revelations; is 3 that right? 4 A. It may be, yes. 5 Q. Did you have any personal 6 involvement in that audit? 7 A. As I said before, I don't 8 recall. 9 But, again, given that this 10 was part of a region where, you know -- 11 first, China, China being, by itself, 12 audited by Chinese auditors for the most 13 part; India, audited by Indian auditors 14 for the most part. I had an interest. I 15 don't recall if I specifically looked at 16 that audit report. 17 Q. That's fair and 18 understandable. 19 And you joined Teva -- was 20 it 2017? 21 A. September 2017. 22 Q. So for audits conducted 23 prior to your joining Teva, did you go 24 back and review audit reports of, say,</p>	<p>Page 376</p> <p>1 at Teva, any quality or compliance issues 2 with the Teva Jerusalem facility? 3 A. Internal quality and 4 compliance issues? 5 Q. Yes. 6 A. Not anything that would be 7 out of the order in terms of, you know, 8 issues and recommendations. 9 Q. Do you recall there ever 10 being any issues regarding the testing 11 methods of incoming API that the 12 Jerusalem facility employed? 13 A. No, I don't recall any 14 issues around that. 15 MR. STANOCH: I'll mark this 16 as the next exhibit, Teva-156. 17 It's Bates ending 83812. 18 - - - 19 (Whereupon, Exhibit 20 Teva-156, 21 TEVA-MDL2875-00083812-3877, 22 6/15/16 E-mail, Myers to Cheasty, 23 was marked for identification.) 24 - - -</p>
<p>Page 375</p> <p>1 ZHP and Mylan for years predating your 2 arrival at the company? 3 A. Probably not. 4 MR. STANOCH: Let's take a 5 quick break off the record. 6 VIDEO TECHNICIAN: The time 7 is now 3:56 p.m. Going off the 8 record. 9 - - - 10 (Whereupon, a brief recess 11 was taken.) 12 - - - 13 VIDEO TECHNICIAN: The time 14 is now 4:07 p.m. Back on the 15 record. 16 BY MR. STANOCH: 17 Q. Mr. Barreto, I think we 18 talked about, earlier, that Teva's 19 Jerusalem, Israel, facility was receiving 20 Mylan API and manufacturing it into 21 valsartan finished dose for the U.S. 22 market, right? 23 A. That is correct. 24 Q. Do you recall, when you were</p>	<p>Page 377</p> <p>1 BY MR. STANOCH: 2 Q. Tell me when you can see it, 3 sir. 4 A. Yes, just let me make sure 5 it uploads. The Internet seems to be 6 working much better. Let's see if I'm 7 correct. Still uploading, counsel. 8 Yes. 9 Q. The first page is a cover 10 e-mail from a Linda Myers, dated June 11 15th, 2016, and she's attaching a copy of 12 a GRA audit for Teva Jerusalem. 13 Do you see that? 14 A. Yes. 15 Q. And if you flip it over, 16 it's the Teva audit of its own Jerusalem 17 facility for an audit conducted in 18 February 2015. 19 Do you see that? 20 A. Okay. Yes, I see it. 21 Q. And I know this predates 22 your arrival at Teva, right? 23 A. That is correct. 24 Q. And have you seen this audit</p>

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1 report before?
2 A. I don't think so.
3 Q. And among the observations
4 that Teva made of its own Jerusalem
5 facility -- if you can flip to the page
6 ending 83872.
7 A. Excuse me, Page 8?
8 Q. Page 60 of 65, Bates number
9 ending --
10 A. Oh, I see. I see. 60 of
11 65. I'm going there. Allow me a second.
12 It's a long report.
13 Did you say 60 of 65?
14 Q. I did, sir.
15 A. Okay. 60 of 65. I'm there,
16 sir.
17 Q. The first sentence --
18 MS. LOCKARD: I'm just going
19 to object to the extent this is
20 outside of the scope of the
21 30(b)(6) notice.
22 But if he has personal
23 knowledge, he can answer.
24 BY MR. STANOCH:

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1 Q. So the page begins,
2 According to SOP 00292.
3 Do you see that?
4 A. I'm reading that, yes.
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
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11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 Q. And do you know whether
22 personally, or in your role as Teva's
23 quality executive, whether -- what
24 follow-up, if any, occurred at the Teva

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1 Jerusalem facility concerning this
2 observation?
3 A. This is the first time that
4 I'm looking at this. So I would have to
5 look at the response that the Teva
6 Jerusalem facility made with respect to
7 this.
8 Q. That's fair. I'm going to
9 mark another exhibit.
10 A. Yes.
11 Q. Stand by.
12 MR. STANOCH: Teva
13 Exhibit-157. Bates ending 246006.
14 - - -
15 (Whereupon, Exhibit
16 Teva-157,
17 TEVA-MDL2875-00495893-5896,
18 3/27/19 E-mail, Vanderween to
19 Barreto, was marked for
20 identification.)
21 - - -
22 BY MR. STANOCH:
23 Q. Tell me when it pops up on
24 your screen, sir.

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1 A. I have it.
2 Q. And this is an e-mail from
3 Inna Reitman, February 1, 2017, to David
4 Hatt.
5 Do you see that?
6 A. Let me look at it, because
7 it's at the bottom, right? It's at the
8 beginning of the string?
9 Q. It's just at the first page.
10 A. Let me look at it. Let me
11 see.
12 Q. I'm looking at this --
13 A. Birk from --
14 MS. LOCKARD: The e-mail I
15 see is --
16 THE WITNESS: It's a
17 different one.
18 MS. LOCKARD: -- Birk
19 Vanderweeen to Eric Drape.
20 THE WITNESS: That's why I
21 was having a little bit of an
22 issue.
23 BY MR. STANOCH:
24 Q. Well, put that one aside.

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1 MR. STANOCH: And I'll mark
2 this. I must have clicked on the
3 wrong button. I was doing so well
4 all day, sir. I apologize.
5 THE WITNESS: I was just a
6 little confused.
7 MR. STANOCH: No, no. Let
8 me mark this. I wish there was a
9 way to mark it inside the system.
10 Let's try this, Teva-158.
11 - - -
12 (Whereupon, Exhibit
13 Teva-158, TEVA-MDL2875-00246006,
14 2/1/17 E-mail, Reitman to Hatt,
15 was marked for identification.)
16 - - -
17 THE WITNESS: Let me go
18 there.
19 MR. STANOCH: That's the
20 same thing, isn't it? That's the
21 same thing.
22 THE WITNESS: It's
23 uploading, so I cannot tell you,
24 counsel.

Page 384

1 It is the same thing.
2 MR. STANOCH: 159, the third
3 time is the charm, sir. I think I
4 got it now. It looks like this.
5 - - -
6 (Whereupon, Exhibit
7 Teva-159, TEVA-MDL2875-00246006,
8 2/1/17 E-mail, Reitman to Hatt,
9 was marked for identification.)
10 - - -
11 THE WITNESS: So let me go
12 back now to -- you want the
13 display from your screen?
14 BY MR. STANOCH:
15 Q. I can do it either way. I
16 can leave this up. Whatever is easier
17 for you, sir.
18 A. No, no. Go ahead. I'll
19 follow you.
20 Q. This Exhibit-158, Bates
21 ending 246006, it's an e-mail from Inna
22 Reitman to David Hatt, February 1, 2017,
23 yes?
24 A. Yes.

Page 385

1 Q. Do you know who Inna Reitman
2 is?
3 A. She was one of the auditors
4 from David Hatt's organization at the
5 time.
6 Q. And what was David Hatt's
7 function vis-à-vis your function when you
8 arrived at Teva? Did he report to you?
9 A. So David -- he reported to
10 me, correct.
11 Q. And was he sort of head of
12 audit? Was that what his job was?
13 A. He was a director of quality
14 audits, and -- yes.
15 Q. And this is attaching
16 another Teva audit report of the Teva
17 Jerusalem facility. This one is from an
18 audit performed in December of 2016.
19 Do you see that?
20 A. Yes, which predates me.
21 Yes.
22 Q. Right. Then among other
23 things that they list here on page ending
24 112 is about quality agreements.

Page 386

[REDACTED]

Page 388

[REDACTED]

Page 387

[REDACTED]

Page 389

[REDACTED]

Page 390

[REDACTED]

Page 392

[REDACTED]

Page 391

[REDACTED]

Page 393

[REDACTED]

Page 394

[REDACTED]

Page 396

1 Q. You don't know, one way or
2 the other, though, for sure whether any
3 of these deficiencies were corrected,
4 when or by whom; is that fair?
5 MS. LOCKARD: Objection.
6 Outside the scope of the 30(b)(6)
7 notice. Personal knowledge.
8 THE WITNESS: I wouldn't
9 know.
10 BY MR. STANOCH:
11 Q. And between these two Teva
12 audits, were you aware of any FDA
13 inspection of the Teva Jerusalem facility
14 in or about 2015 or 2016?
15 A. I don't recall. But more
16 than likely -- I want to say I think
17 there was one in 2017, yes.
18 Yes. Because if I recall
19 well, I actually visited the site -- was
20 it 2017 or 2018?
21 Q. 2019.
22 A. It could have been in 2019.
23 Q. We'll get to that. Let's
24 stick in the 2015, '16 range, okay.

Page 395

[REDACTED]

3 MS. LOCKARD: Objection.
4 Vague.
5 MR. STANOCH: You can
6 answer.
7 THE WITNESS: It would be
8 applicable to the valsartan
9 product.
10 BY MR. STANOCH:
11 Q. Are you aware of any
12 follow-up that was done to correct those
13 or the other deficiencies identified in
14 this report?
15 A. Since this happened before
16 my time, the only thing I can tell you is
17 there are procedures in place for
18 addressing these type of observations.
19 And in the event of critical observation,
20 that also gets a much higher level of
21 attention.
22 So I have to say that if the
23 procedure was followed, those
24 deficiencies were corrected.

Page 397

1 A. Okay.
2 MR. STANOCH: The next
3 exhibit, Teva-160.
4 - - -
5 (Whereupon, Exhibit
6 Teva-160,
7 TEVA-MDL2875-00400799-0905,
8 6/13/19 E-mail, Hoover to Hatt,
9 was marked for identification.)
10 - - -
11 BY MR. STANOCH:
12 Q. It should look like this on
13 the first page.
14 MR. STANOCH: For the record
15 it's Bates ending 400799.
16 THE WITNESS: If you want to
17 proceed with guiding through your
18 screen, I'll be okay with that.
19 BY MR. STANOCH:
20 Q. Very good, sir.
21 The cover is an e-mail from
22 Ms. Linda Hoover to David Hatt and Sean
23 Israel, dated June 13th, 2019.
24 Do you see that?

Page 398

1 A. Yes.

[REDACTED]

Page 400

[REDACTED]

23 Q. I think you said before,

24 when your counsel was shuffling papers,

Page 399

[REDACTED]

Page 401

1 you don't want the analysts manipulating

2 the data, right?

3 A. That is --

4 MS. LOCKARD: Objection to

5 form or the suggestion that I

6 intentionally manipulated the

7 papers. That's not appropriate,

8 David.

9 MR. STANOCH: I wasn't

10 suggesting you did anything. I

11 was saying you were rustling

12 papers. And I heard him say, you

13 don't want analysts manipulating

14 the data. And I was just

15 confirming that, counsel.

16 BY MR. STANOCH:

17 Q. And the answer is yes,

18 correct?

[REDACTED]

Page 402

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 Q. Sure. But, generally
14 speaking, training of employees on their
15 functions to comply with GMP, that's
16 something that's required of a drug
17 manufacturer like Teva, right?
18 A. That is correct. And I'm
19 also aware that training is provided on a
20 continuous basis to employees.
21 Q. And it seems here, though,
22 the FDA was disagreeing with that
23 supposition of yours and saying that
24 training was not given at the Jerusalem
facility, at least at the time of their

Page 403

1 inspection in 2015; is that right?
2 A. I would have to look at the
3 details of the way in which the
4 investigator interpreted and concluded
5 that training was not provided.
6 Q. You would agree that
7 regardless -- I don't have it because
8 things are redacted here by Teva.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 A. And what I'm trying to say
19 is what I'm missing here, which would
20 allow me to give you a much better
21 description, is the details as to what is
22 it exactly that the investigator was
23 objecting to.
24 Because most observations

Page 404

1 start with this type of general template
2 description, which is not necessarily the
3 detail that I -- that I would be
4 interested in.
5 Q. Some of the detail may
6 appear in -- for example, under the area
7 that says, Supporting evidence and
8 relevance.
9 A. Could have been.
10 Q. Could have been.
11 We don't know because it's
12 redacted, right?
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
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21 [REDACTED]
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24 [REDACTED]

Page 405

1 [REDACTED]
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24 [REDACTED]

Page 406

1 [REDACTED]
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3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 Q. Do you know whether or not
14 the, as you sit here today, if the FDA
15 accepted those responses as adequate?
16 A. We continued to manufacture
17 post that inspection, as far as I know,
18 and we continued to distribute to the
19 United States. So that tells me that the
20 FDA found the corrective actions to be
21 acceptable.
22 Q. But you don't know, one way
23 or the other, for sure if the FDA
24 found -- well, first of all, you don't

Page 407

1 know what corrective actions, if any,
2 were taken, number one, right?
3 A. What I'm saying to you is
4 that knowing the procedures and from my
5 experience, I can assure you that a
6 written response was generated, based on
7 my understanding and my more than 40
8 years of experience in this field.
9 If you don't submit a
10 response, then your facility is
11 classified as unacceptable. If a
12 facility is acceptable, it can continue
13 to manufacture. So there was a response.
14 Q. But you haven't seen the
15 response?
16 A. That is correct. That was
17 prior to my time.
18 Q. Sure. That's fair. Stand
19 by.
20 MS. LOCKARD: So we're on --
21 so we've now been going for 30
22 minutes, unless you want to get
23 through something else?
24 MR. STANOCH: Yeah, let me

Page 408

1 just get through one more
2 document, Ms. Lockard. I think
3 that will round out this specific
4 subject matter. If you're okay
5 with that, Mr. Barreto.
6 THE WITNESS: Absolutely.
7 MR. STANOCH: You okay, Ms.
8 Lockard?
9 MS. LOCKARD: Sure. Sure.
10 MR. STANOCH: Teva-161.
11 Bates ending 67532.
12 - - -
13 (Whereupon, Exhibit
14 Teva-161,
15 TEVA-MDL2875-00067532-7537, 1/1/19
16 E-mail, Weissbazak to Denac, was
17 marked for identification.)
18 - - -
19 BY MR. STANOCH:
20 Q. I will share my screen again
21 to move it along.
22 You're seeing the same thing
23 I have here?
24 A. Yes, sir.

Page 409

1 Q. The topmost e-mail here is
2 one in a chain from an Liron Weissbazak
3 to yourself and others at Teva, dated
4 August 1, 2019.
5 Do you see that?
6 A. Yes, I do remember that
7 inspection.
8 Q. And it references an FDA
9 inspection of the Jerusalem site; is that
10 right?
11 A. That is correct.
12 Q. And this is the same Teva
13 Jerusalem site that we've been talking
14 about that manufactured valsartan
15 finished dose for the U.S. market, right?
16 A. That is correct.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 410

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 Q. And we've talked about,
5 today, valsartan recalls and the
6 investigation into the valsartan NDMA
7 contamination and other nitrosamine
8 contamination, right?
9 A. Yes.
10 Q. And we've talked about, a
11 little bit, vendor qualification and
12 specifically reduced testing as it
13 related to the API that Teva Jerusalem
14 was purchasing from Mylan, correct?
15 A. Correct.
16 Q. And do you -- you said you
17 recall this audit; is that right?
18 A. Yes, I do.
19 Q. And you were on the ground
20 for this one; is that what you said
21 earlier?
22 A. I was -- I was on the
23 ground, yes.
24 Q. And were valsartan-related

Page 411

1 issues and nitrosamine issues discussed
2 with the FDA auditors during this audit?
3 A. They had an interest in
4 having a discussion around, yeah, the
5 recalls and investigations associated
6 with the nitrosamine, yes.
7 Q. What did Teva discuss with
8 the FDA auditors during this July 2019
9 FDA inspection of the Teva Jerusalem
10 facility?
11 A. We shared with them
12 analytical tests results; we shared with
13 them the activities associated with the
14 investigations that were performed,
15 associated with, you know, their receipt
16 and manufacturing activities with
17 valsartan; we gave them details about the
18 recall action that was taken; that sort
19 of discussion.
20 Q. And were -- it looks like
21 there was an attachment, a PDF, here.
22 Were notes circulated after
23 each day of this -- I think it was a
24 five-day audit, circulated amongst Teva

Page 412

1 personnel?
2 A. Yes.
3 Q. And that was about the FDA's
4 inspection and potentially its
5 discussions with Teva about the valsartan
6 and nitrosamines issues, right?
7 A. Correct.
8 Q. Can you tell me, do you
9 recall any specifics in terms of what was
10 said to or by the FDA inspectors
11 concerning the valsartan issues and
12 nitrosamine contamination?
13 A. I don't recall the
14 specifics. But if I recall well from the
15 outcome of that inspection, the
16 inspectors had no concerns with respect
17 to the work that we had done.
18 Q. As of this time, now a year
19 after the first recalls happened, this is
20 now August 2019, right?
21 A. It's looking -- doing a
22 retrospective review.
23 Q. Right.
24 MR. STANOCH: Ms. Lockard,

Page 413

1 the attachment to this particular
2 e-mail was withheld. And, in
3 fact, I don't think we have copies
4 of any of the other notes or
5 inspection-related documents for
6 this.
7 I think it's relevant and
8 discoverable, so we're going to
9 request it.
10 MS. LOCKARD: I'll take a
11 look at that and get a response
12 back to you.
13 MR. STANOCH: Thank you.
14 Why don't we adjourn for the
15 day, counsel, and, Mr. Barreto?
16 THE WITNESS: That will be
17 fine, sir.
18 MR. STANOCH: Okay.
19 VIDEO TECHNICIAN: The time
20 is now 4:42 p.m. Going off the
21 record.
22 - - -
23
24

Page 414

1 - - -
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 3 (Whereupon, the deposition
 4 adjourned at 4:42 p.m.)
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Page 416

1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition
 4 over carefully and make any necessary
 5 corrections. You should state the reason
 6 in the appropriate space on the errata
 7 sheet for any corrections that are made.
 8 After doing so, please sign
 9 the errata sheet and date it.
 10 You are signing same subject
 11 to the changes you have noted on the
 12 errata sheet, which will be attached to
 13 your deposition.
 14 It is imperative that you
 15 return the original errata sheet to the
 16 deposing attorney within sixty (60) days
 17 of receipt of the deposition transcript
 18 by you. If you fail to do so, the
 19 deposition transcript may be deemed to be
 20 accurate and may be used in court.
 21
 22
 23
 24

Page 415

1 CERTIFICATE
 2
 3
 4 I, Amanda Maslynsky-Miller, Certified
 5 Realtime Reporter, do hereby certify that
 6 prior to the commencement of the
 7 examination, DANIEL BARRETO, was remotely sworn
 8 by me to testify to the truth, the whole
 9 truth and nothing but the truth.
 10
 11 I DO FURTHER CERTIFY that the foregoing is a
 12 verbatim transcript of the testimony as
 13 taken stenographically by me at the time,
 14 place and on the date hereinbefore set
 15 forth, to the best of my ability.
 16
 17 I DO FURTHER CERTIFY that I am neither a
 18 relative nor employee nor attorney nor
 19 counsel of any of the parties to this
 20 action, and that I am neither a relative nor
 21 employee of such attorney or counsel, and
 22 that I am not financially interested in the
 23 action.
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<div>Page 418</div> <div>1 ACKNOWLEDGMENT OF DEPONENT</div> <div>2</div> <div>3 I, _____, do</div> <div>4 hereby certify that I have read the</div> <div>5 foregoing pages, 1 - 414, and that the</div> <div>6 same is a correct transcription of the</div> <div>7 answers given by me to the questions</div> <div>8 therein propounded, except for the</div> <div>9 corrections or changes in form or</div> <div>10 substance, if any, noted in the attached</div> <div>11 Errata Sheet.</div> <div>12</div> <div>13 _____ 14 DANIEL BARRETO DATE</div> <div>15</div> <div>16 Subscribed and sworn</div> <div>17 to before me this</div> <div>18 _____ day of _____, 20____.</div> <div>19</div> <div>20 My commission expires: _____</div> <div>21</div> <div>22 _____ 23 Notary Public</div> <div>24</div>	
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Exhibit 90

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 - - -
3 IN RE: VALSARTAN, : MDL NO. 2875
4 LOSARTAN, AND :
5 IRBESARTAN PRODUCTS : HON. ROBERT
6 LIABILITY LITIGATION : B. KUGLER
7 - - -
8 - - -
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10 June 30, 2021
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IN RE: VALSARTAN, : MDL NO. 2875
LOSARTAN, AND :
IRBESARTAN PRODUCTS : HON. ROBERT
LIABILITY LITIGATION : B. KUGLER

THIS DOCUMENT APPLIES :
TO ALL CASES :

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

June 30, 2021

Videotaped remote deposition of
JENS NASSALL, taken pursuant to notice,
was held via Zoom Videoconference,
beginning at 12:02 p.m., (Central
European Summer Time) on the above date,
before Michelle L. Gray, a Registered
Professional Reporter, Certified
Shorthand Reporter, Certified Realtime
Reporter, and Notary Public.

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 I N D E X
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Testimony of:

JENS NASSALL

By Mr. Stanoch 12
 By Ms. Lockard 330

- - -
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 - - -

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13	Teva-325	E-mail thread 7/27/2018, Subject is Valsartan - second wave test results from Huahai	211
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21	Teva-327	E-mail thread 8/9/2018, Subject is Urgent: Valsartan update	224
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<p style="text-align: right;">Page 10</p> <p style="text-align: center;">- - - DEPOSITION SUPPORT INDEX - - -</p> <p>Direction to Witness Not to Answer PAGE LINE None.</p> <p>Request for Production of Documents PAGE LINE None.</p> <p>Stipulations PAGE LINE None.</p> <p>Questions Marked PAGE LINE None.</p>	<p style="text-align: right;">Page 12</p> <p>parties are heard completely. All counsel present will be noted on the stenographic record. The court reporter is Michelle Gray and will now swear in the witness.</p> <p style="text-align: center;">- - -</p> <p>... JENS NASSALL, having been first duly sworn, was examined and testified as follows:</p> <p style="text-align: center;">- - -</p> <p style="text-align: center;">EXAMINATION</p> <p style="text-align: center;">- - -</p> <p>BY MR. STANOCH: Q. Hello, Mr. Nassall, we met a moment ago. My name is David Stanoch, I'm one of the lawyers for the plaintiffs in this action. I will be asking you questions today. A. Nice to meet you. Q. Same. Have -- I'll add, thank you for appearing remotely from Europe for this deposition.</p>
<p style="text-align: right;">Page 11</p> <p style="text-align: center;">- - -</p> <p>THE VIDEOGRAPHER: We are now on the record. My name is Ingrid Rodriguez. I'm a videographer for Golkow Litigation Services. Today's date is June 30, 2021, and the time is 12:02 p.m. This remote video deposition is being held in the matter of In Re valsartan, losartan, and irbesartan products liability litigation for the United States District Court, District of New Jersey. The deponent is Jens Nassall. All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely. Due to the nature of remote reporting, please pause briefly before speaking to ensure all</p>	<p style="text-align: right;">Page 13</p> <p>A. You're welcome. Q. Have you been deposed before, sir? A. No, I have not. Q. I will go over some of the rules for today's deposition. I'm sure you are familiar with these from your own counsel. As I'm sure you are aware, I will be asking you a series of questions and you will be providing answers. Everything everyone says will be taken down by the court stenographer, as well as the videographer. Do you understand that? A. Yes, I do. Q. Because everything is being taken down, I will try to pause before I speak so I don't speak over you. I'd ask if you try to do the same so we don't speak at the same time. Is that fair? A. That's fair. Q. If you do not understand one of my questions, please say so. I'll</p>

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1 attempt to rephrase. Otherwise I will
2 assume you understood my question. Is
3 that fair?
4 A. That's fair as well.
5 Q. From time to time your
6 attorney may object. You should still
7 answer the question unless she instructs
8 you otherwise. Do you understand that?
9 A. Yes, I do.
10 Q. We can take breaks
11 throughout the day. This is not an
12 endurance test. I just ask that if a
13 question is pending, answer the question,
14 and then we can take a break. Okay?
15 A. Okay.
16 Q. And is there any reason why
17 you cannot testify truthfully and
18 accurately today?
19 A. No.
20 Q. And you understand you're
21 under oath to tell the truth today,
22 right?
23 A. Yes, I do.
24 Q. And I also understand or --

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1 strike that.
2 You understand that you are
3 also testifying on behalf of Teva as to
4 certain topics; is that right?
5 A. Yes, for certain topics I
6 do.
7 Q. Stand by, I'm going to
8 attempt to mark the first exhibit, sir.
9 A. Okay.
10 (Document marked for
11 identification as Exhibit
12 Teva-315.)
13 BY MR. STANOCH:
14 Q. Sir, I've just marked
15 Exhibit 315. You should have access to
16 that in the documents folder. Let me
17 know when you can see it.
18 A. All right. I see it in the
19 folder. Give me a moment. Yes, it
20 opened.
21 Q. Great. This appears to be a
22 copy of the deposition notice for your
23 deposition today, right?
24 A. Yes, it does.

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1 Q. You've seen this before,
2 right?
3 A. Yes, I did.
4 Q. And if you scroll, there's
5 some topics listed there beginning with
6 44. Do you see that?
7 A. Yes, I see.
8 Q. Either you or Ms. Lockard,
9 you can stipulate too, what topics are
10 you prepared to testify on today on
11 behalf of Teva of those listed here?
12 I can -- or Mr. Nassall,
13 which of these -- which of these topics
14 are you prepared to testify on behalf of
15 Teva today?
16 A. Let me check. Impurity --
17 sorry. I need to read them.
18 Q. Sure.
19 A. I can't recall the number by
20 heart.
21 Q. Sure.
22 A. So I remember it's
23 Number 48, Teva's product recall for
24 valsartan finished dose, including who

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1 Teva communicated with, how, about what,
2 and the retention of recalled or
3 sequestered valsartan finished dose. And
4 this topic I can cover on the API level.
5 Then it's Teva oral and
6 written communication with ZHP with
7 regard to the valsartan API, and the same
8 with Mylan.
9 Q. That would be topic, listed
10 here, 44 and 45, correct?
11 A. Yes. Correct.
12 Q. And the one you mentioned
13 earlier was Topic 48, correct?
14 A. Yes, correct.
15 Q. And I understand you're also
16 prepared to testify on Topic 49 to the
17 extent it relates to indemnifications
18 paid or provided by or to Teva in
19 connection with the nitrosamine impurity
20 within valsartan?
21 A. Yes, that sounds correct.
22 Q. I believe that you are not
23 prepared today to testify on behalf of
24 Teva as to Topics 46 and 47; is that

Page 18

1 correct?

2 MS. LOCKARD: We just object

3 to form. He's not being offered

4 for those.

5 MR. STANOCH: That's fine.

6 BY MR. STANOCH:

7 Q. Is that correct?

8 A. So that's correct, I will

9 not testify for 46 and 47.

10 Q. Okay. What did you do --

11 strike that.

12 What did you do to prepare

13 for today's deposition, sir?

14 A. I had some meetings with our

15 lawyers, reviewed some documents. So I

16 tried recalling.

17 Q. When did you first learn

18 that you were going to be a potential

19 deponent in this litigation

20 approximately?

21 A. Approximately a few months

22 ago.

23 Q. And you said you had some

24 meetings with your counsel to prepare for

Page 19

1 today's deposition.

2 Approximately how many

3 meetings have you had with your counsel

4 to prepare for today's deposition?

5 A. Approximately four, five.

6 Q. Were those all remote or

7 were any of those in person?

8 A. They were all remote.

9 Q. And the only people at those

10 meetings besides yourself was that Teva

11 inhouse or outside counsel?

12 A. Yes. Correct.

13 Q. Did you ever have any

14 meetings to prepare for today's

15 deposition with any nonlawyers?

16 A. No, I did not.

17 Q. You did not talk to any

18 colleagues to get any information to

19 prepare for today's deposition, nonlawyer

20 colleagues?

21 A. No, I didn't.

22 Q. Approximately how many

23 documents did you review to prepare for

24 today's deposition?

Page 20

1 A. Approximately 50.

2 Q. Between meetings with your

3 counsel and your own review of documents,

4 how much time roughly would you say you

5 spent preparing for today's deposition?

6 A. You mean how much time I

7 spend with the counsel or by myself?

8 Q. Oh. You can do each

9 separately and then altogether, sir.

10 A. I would say with a

11 counselor, must have been 15 hours

12 roughly, probably. And then I've -- I'm

13 not sure, a few more hours reading some

14 of the documents.

15 Q. That's fine. All right.

16 Thank you.

17 You can put that exhibit

18 aside.

19 MR. STANOCH: I'm going to

20 mark the next exhibit, sir, to go

21 over some of your educational and

22 professional background. All

23 right?

24 BY MR. STANOCH:

Page 21

1 Q. All right?

2 A. All right.

3 (Document marked for

4 identification as Exhibit

5 Teva-316.)

6 BY MR. STANOCH:

7 Q. Teva 316. Let me know when

8 you can access that.

9 A. Yes, I opened it.

10 Q. This appears to be a copy of

11 your resumé or CV, as well as your

12 LinkedIn profile?

13 A. Let me shortly scroll

14 through it. CV and the LinkedIn profile,

15 yes.

16 Q. Did you prepare both the CV

17 and the LinkedIn profile?

18 A. Yes.

19 Q. And you can refer to these

20 as we go through, I just want to get some

21 basic background of your education and

22 professional work. Okay?

23 A. Okay.

24 Q. And it looks like you --

<p style="text-align: right;">Page 22</p> <p>1 help me out some education. From what 2 university did you graduate for what 3 would be equivalent of a four-year 4 college in the United States? 5 A. I'm not fully sure about the 6 four-year U.S. version. 7 Q. That's fine. 8 A. But the main graduation was 9 from University of Konstanz with a 10 chemistry diploma, which is nowadays a 11 master degree. 12 Q. I see. And then you went to 13 Technical University of Munich? 14 A. Yes, I did, where I started 15 my Ph.D. and continued that in -- at the 16 Technical University of Chemnitz, as my 17 professor who was guiding me through my 18 Ph.D. thesis moved to Chemnitz. 19 Q. I see. And then did you 20 obtain your Ph.D. from Chemnitz? 21 A. No, I did not. 22 Q. And that would have -- that 23 was -- well, what was the area of focus 24 for your Ph.D. when you were studying?</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. And then did you obtain a 2 couple of postgraduate degrees from 3 University of Hagen, H-A-G-E-N; is that 4 right? 5 A. Yes. 6 Q. And those were in what 7 fields? 8 A. Those were in the fields of 9 business and labor law and economics. 10 Q. You obtained certificates or 11 the equivalent for those studies? 12 A. For those, no, I never 13 finished. I just joined some lectures. 14 No. 15 Q. Understood. Your first, I 16 guess, true professional job was at 17 ratiopharm; is that correct? 18 A. Yes, that's correct. 19 Q. And you can refer to your 20 resumé or LinkedIn here. But just 21 generally tell us what you were doing 22 when you first joined ratiopharm? 23 A. Ok. When I first joined 24 ratiopharm, my official job title was</p>
<p style="text-align: right;">Page 23</p> <p>1 A. For the Ph.D., it was this 2 thesis on new catalysts for oxidations, 3 which was meant to be used mainly in 4 detergents; there are some catalysts 5 helping removing stains. 6 Q. Have you continued to pursue 7 classes from 2003 to obtain the Ph.D.? 8 A. I mean the classes, and the 9 practical work which needs to be done in 10 the lab was completed in 2003. So I did 11 not attend any further classes. 12 Q. And I'm sorry, I think you 13 said that you did not complete and were 14 not awarded the Ph.D.? 15 A. No, the -- the last step in 16 obtaining a Ph.D. in Germany is writing 17 down the thesis, hand it in, and then 18 defend it. That never happened. The 19 idea was to do that while I had my first 20 position at ratiopharm and somehow there 21 never was any time left. 22 Q. You went to work for a 23 pharmaceutical company, correct? 24 A. Yes, that's correct.</p>	<p style="text-align: right;">Page 25</p> <p>1 licensing manager, and the main tasks 2 were in-licensing finished product and 3 doses, usually together with the product 4 supply which then ratiopharm was 5 marketing mainly in Germany and also some 6 other European countries. 7 Q. Was licensing, so you were 8 working to get the legal rights to obtain 9 certain molecules or treatments? 10 A. Yes. Ratiopharm's R&D 11 capabilities for finished dosage form was 12 limited, but what ratiopharm did was 13 still offering more or less a complete 14 generic portfolio in Germany and some 15 other European countries. And then most 16 of these products were developed by 17 external partners and we in-licensed the 18 rights. They also supplied the product, 19 and then after a while, usually 20 production was moved from the external 21 partners to inhouse production at 22 ratiopharm. 23 Q. I see. And then around 24 February 2007 you went to work briefly</p>

<p style="text-align: right;">Page 26</p> <p>1 for another company; is that right?</p> <p>2 A. Yes, that's correct. I went</p> <p>3 from another German generic company owned</p> <p>4 by Torrent.</p> <p>5 Q. And were you doing generally</p> <p>6 the same types of licensing activities</p> <p>7 while you were at Heumann?</p> <p>8 A. Yes, I was. In general,</p> <p>9 same tasks, responsibilities were a</p> <p>10 little wider. The company was a little</p> <p>11 bit smaller, so less people, and that was</p> <p>12 the interesting part there.</p> <p>13 Q. And then it looks like you</p> <p>14 returned to, is it ratiopharm?</p> <p>15 A. Yes. I did.</p> <p>16 Q. And what position did you</p> <p>17 return, it looks like in January of 2008?</p> <p>18 A. Yes. Ratiopharm wanted me</p> <p>19 back and offered me the position of chief</p> <p>20 representative at the ratiopharm office</p> <p>21 in Shanghai. So this was not in</p> <p>22 licensing anymore. It was leading</p> <p>23 procurement of materials from Southeast</p> <p>24 Asia.</p>	<p style="text-align: right;">Page 28</p> <p>1 Korea, Taiwan. That's mainly it.</p> <p>2 Q. Okay. And then you have</p> <p>3 listed here that you began working in</p> <p>4 January of 2011 for Teva Generics Systems</p> <p>5 in Ulm, Germany, correct?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. And at this time was</p> <p>8 ratiopharm acquired by Teva, or was Teva</p> <p>9 a standalone company at the time?</p> <p>10 A. No. While I was -- it</p> <p>11 happened during 2010, that Teva acquired</p> <p>12 ratiopharm and Merckle, the two German</p> <p>13 companies which I was working for.</p> <p>14 Q. Got it. So you didn't leave</p> <p>15 ratiopharm to go work somewhere else --</p> <p>16 A. No.</p> <p>17 Q. -- where you were working</p> <p>18 was acquired essentially?</p> <p>19 A. Yes, correct.</p> <p>20 Q. And you can -- you can tell</p> <p>21 me, but it looks like you had some of the</p> <p>22 same responsibilities in sourcing that</p> <p>23 you had while it was ratiopharm itself;</p> <p>24 is that right?</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. The materials included API,</p> <p>2 the active pharmaceutical ingredient?</p> <p>3 A. Yes.</p> <p>4 Q. What other materials did</p> <p>5 your role encompass?</p> <p>6 A. There were also some</p> <p>7 packaging materials, promotional</p> <p>8 materials. We also worked on some</p> <p>9 finished dosage forms. But the main part</p> <p>10 was the API.</p> <p>11 Q. And the API that you were</p> <p>12 responsible for sourcing during this</p> <p>13 time, was then made into finished dose</p> <p>14 at -- for ratiopharm and other</p> <p>15 facilities?</p> <p>16 A. Yes, correct. At ratiopharm</p> <p>17 production facilities.</p> <p>18 Q. And Southeast Asia, you</p> <p>19 don't -- I don't need perfection, but</p> <p>20 generally what countries did your</p> <p>21 territory encompass at the time?</p> <p>22 A. The main sourcing came from</p> <p>23 People's Republic of China. And there</p> <p>24 were also some manufacturers in South</p>	<p style="text-align: right;">Page 29</p> <p>1 A. It's not exactly the same.</p> <p>2 During the ratiopharm time in China, I</p> <p>3 was responsible to lead the team buying</p> <p>4 the materials in Southeast Asia.</p> <p>5 Then when it was Teva</p> <p>6 Generics Systems, it was R&D sourcing.</p> <p>7 So it was no longer commercial -- or no</p> <p>8 longer material for commercial production</p> <p>9 but for the R&D activities of Teva. And</p> <p>10 the responsibility was to get the</p> <p>11 materials needed by the European R&D</p> <p>12 sides of Teva.</p> <p>13 And there were also some --</p> <p>14 some R&D sites outside of Europe so I did</p> <p>15 not take care of that. And it was then</p> <p>16 sourcing from global suppliers, not only</p> <p>17 from Asia.</p> <p>18 Q. I see. Thank you.</p> <p>19 And just so we are clear,</p> <p>20 sourcing for R&D, you were obtaining API</p> <p>21 for products that Teva had not yet began</p> <p>22 to sell in a particular market. Is that</p> <p>23 fair?</p> <p>24 A. Yes. That's fair to say.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q. And commercialized product, 2 that means the product is sort of 3 approved and everything else is okay for 4 Teva is then selling the finished dose 5 product in a given market. Is that fair? 6 A. Yes, that's fair. 7 Q. Thanks. 8 So at this time you were 9 sourcing for the R&D side of Teva only? 10 A. Correct, for the European 11 Teva R&D sites, yes. 12 Q. And then it looks like 13 around May 2014, you became director 14 global API category strategy at Teva, 15 correct? 16 A. Yes, that's correct. 17 Q. And tell me how your 18 responsibilities changed when you assumed 19 that position. 20 A. That was then again more on 21 the commercial demand of API and 22 developing the strategies of -- from 23 which suppliers we want to source, which 24 API. So this is, again, then less of the</p>	<p style="text-align: right;">Page 32</p> <p>1 packaging material. 2 Q. And then it looks like since 3 approximately March 2020, you have 4 another position at Teva, senior director 5 head of global strategy implementation 6 for API, excipients, and raw materials, 7 and China procurement; is that correct? 8 A. Yeah, that's correct. 9 Q. And what do your current -- 10 strike that. 11 You are still in that 12 position today, right? 13 A. Yeah, correct. 14 Q. What do your current 15 responsibilities entail? 16 A. So the responsibilities now, 17 we just structured it a little bit 18 differently. So it's still the direct 19 materials category I'm taking care of 20 with a special focus on how to implement 21 the strategies in all of the Teva sites. 22 So it's a little bit more of internal 23 responsibility. Yeah. 24 Q. Are you focused on R&D or</p>
<p style="text-align: right;">Page 31</p> <p>1 R&D activities, but for commercial 2 production of finished dosage forms. 3 Q. I see. Then you had another 4 position you took in December of 2017, it 5 looks like at a Teva facility in -- for 6 Japan? 7 A. That's correct. That was 8 partly in parallel. So I was also 9 responsible for the procurement in 10 Nagoya, Japan, for the materials. I also 11 stayed for almost a year in Nagoya. 12 Q. I see. And then around 13 March 2019, you came back to Germany as 14 senior director, head of global strategic 15 sourcing? 16 A. Yes, that's correct. 17 Q. And how did your 18 responsibilities change if at all when 19 you assumed that position? 20 A. That was then again more 21 focused on the R&D activities for Teva. 22 At that time then it was for all global 23 Teva R&D sites, and for all materials, 24 not only API but also excipients and</p>	<p style="text-align: right;">Page 33</p> <p>1 commercial or both now? 2 A. The focus is a little bit 3 more on the commercial part. But from 4 time to time it's also involved the R&D 5 area. 6 Q. Throughout your tenure at 7 ratiopharm or Teva, is it fair to say 8 your job responsibilities focused on 9 licensing or sourcing? 10 A. It's fair to say that, yes. 11 Q. But you never had any 12 responsibilities concerning the 13 manufacture of API or finished dose, 14 right? 15 A. Yeah, that's correct. 16 Q. You've never had any 17 responsibilities for the testing of API 18 or finished dose, correct? 19 A. That's as well correct. 20 Q. And you've never had any job 21 responsibilities for quality assurance 22 for API or finished dose, right? 23 A. Correct. No responsibility 24 for that.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q. And you are familiar with 2 the term "GMP," right? 3 A. Yes, I am. 4 Q. And that's good 5 manufacturing practices? 6 A. Correct. 7 Q. And you've never had any job 8 responsibilities for ensuring GMP 9 compliance at ratiopharm or Teva, 10 correct? 11 A. Correct. Never had that. 12 Q. And did you ever have any 13 responsibilities for auditing Teva or 14 ratiopharm suppliers of API? 15 A. Never had any 16 responsibilities for that, no. 17 Q. Okay. And Mr. Nassall, if 18 you can look at your LinkedIn profile too 19 there. Do you see that? 20 A. Yes, I see it. 21 Q. And look, I don't mean to 22 belabor this. These things happen. But 23 some of the dates don't line up for your 24 LinkedIn profile experience and your CV</p>	<p style="text-align: right;">Page 36</p> <p>1 complex, what the organization looks like 2 at Teva. So the CV is for sure the more 3 correct version I would say. 4 Q. Right. And then for senior 5 director global API category head on your 6 LinkedIn, it says May 2018 to 7 February 2019, right? 8 A. Yes. 9 Q. And then it looks like the 10 dates are a little off there. Almost -- 11 this one it looks like it says what, 12 March 2019 to March 2020 on your resumé. 13 A. This is potentially also 14 because that stay in Nagoya was at the 15 same time and somewhere in between, 16 that's not -- not that easy on LinkedIn 17 to cover that correctly, at least my 18 capabilities with that online platform 19 are not at a professional level. 20 Q. Sure. Sure. No, I 21 understand. 22 And then just to round it 23 out, for your senior director head of 24 global API category role in Japan, the</p>
<p style="text-align: right;">Page 35</p> <p>1 experience. Just for instance on your 2 resumé, it says since March 2020 you have 3 been in your current position. On the 4 LinkedIn it says May 2020. Do you see 5 that? 6 A. Wait a second. May 2020. 7 Yes, I see that. That's probably -- as I 8 recall it, it always takes me a little 9 bit longer to update my LinkedIn profile. 10 Q. Sure. Right, right. And 11 there's a couple other, you know, date 12 distinctions as well. If you look on the 13 LinkedIn, it says director global API 14 category strategy October 2015 to 15 April 2018. Do you see that? 16 A. I see that. 17 Q. And then on the resumé, I 18 think it was saying for that position 19 May 2014 and December of 2017. 20 So do you see that? 21 A. Wait a second. May '14 to 22 '17. Yes, I see that. I was probably 23 trying to make it a little bit -- you 24 know, it's pretty -- it can be pretty</p>	<p style="text-align: right;">Page 37</p> <p>1 LinkedIn was March -- March 2019, 2 April '20. It's December 17th to 3 March 2018 in your resumé, right? 4 A. That's because I really 5 stayed in Nagoya from December '17 to 6 May '18. But I was responsible for Teva 7 Takeda for the full time mentioned in the 8 CV. 9 Q. Okay. So it's fair -- it 10 also looks like in education, your time 11 or study at Chemnitz on LinkedIn, it says 12 2000 to 2004. And on your resumé it says 13 2000 to 2003, right? 14 A. Yes. But this is -- I 15 started in April 2004 at ratiopharm. And 16 the real work at the university ended in 17 December 2003 so it's more or less the 18 same. 19 Q. Well, they both say that you 20 started ratiopharm in April 2003, right? 21 A. Yes. 22 Q. Were you studying at 23 Chemnitz at the same time that you were 24 at ratiopharm?</p>

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1 A. That was the time where we
2 were still -- where I still continued
3 communicating with my professor working
4 on the Ph.D. in parallel, because there
5 was the idea that I should finish it and
6 also ratiopharm wanted to give me time to
7 finish it. So it continued for a little
8 longer in parallel, but as I said, it
9 never happened in the end.

10 Q. Right. And, again, I'm not
11 looking to belabor it, Mr. Nassall. Is
12 it fair to say that if I wanted the
13 accurate dates, the CV in this exhibit is
14 the most accurate document, right?

15 A. Yes, that's correct.

16 Q. And just between comparing
17 the CV and the LinkedIn profile right
18 now, and you can take the time if you
19 want, is there anything in your CV that
20 you want to change or update now or does
21 it look good now that you're looking at
22 it at this moment?

23 A. If I looked at the CV?

24 Q. Mm-hmm.

Page 39

1 A. Give me a second.

2 Q. Sure.

3 A. So education, I would keep
4 it exactly as it is. Ratiopharm from
5 April '3 to January '7, then Heumann
6 until December. Then moving to Shanghai
7 for three years. Then it was R&D
8 sourcing. Yeah, I would keep the CV.

9 Q. Okay. Very good.

10 So you understand that this
11 case focuses in large parts on the
12 discovery of nitrosamines in the
13 valsartan API, correct?

14 A. I do understand that, yes.

15 Q. And I wanted to focus in on
16 some time periods from your tenure at
17 ratiopharm in Teva.

18 It looks like again you
19 were -- starting in 2011, you were
20 director of API sourcing R&D at Teva,
21 correct?

22 A. Correct, for the European
23 R&D sites.

24 Q. Right. So from January 2011

Page 40

1 to May 2014, you do not have any
2 responsibilities for sourcing API for any
3 Teva commercialized product; is that
4 right?

5 A. That's right.

6 Q. And you didn't start to have
7 those responsibilities until about
8 May 2014, correct?

9 A. Sorry, give me a second.

10 Q. Sure. Please.

11 A. My Zoom disappeared. I'm
12 not sure why.

13 Ah, there you are.

14 Sorry. Could you repeat the
15 question?

16 Q. Yes. You did not have
17 responsibilities for sourcing API for
18 commercialized product until
19 approximately May 2014, right?

20 A. Yes. Right.

21 Q. And then you would have had
22 responsibilities for sourcing API for
23 commercial products then from May 2014
24 forward?

Page 41

1 A. Yes, correct.

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

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[REDACTED]

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[REDACTED]

Page 48

[REDACTED]

18 Q. And would you negotiate the
19 supply agreements?
20 A. Me and my team, yes, mainly.
21 Q. Sure. I'm sure you had
22 support from other folks within the
23 company, such as legal, et cetera, right?
24 A. Correct.

Page 47

[REDACTED]

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1 Q. And tell me generally again,
2 we're sticking with this January 2011 to
3 May 2014 time period, how you and your
4 team negotiated the pricing for API to be
5 sourced.
6 MS. LOCKARD: I'm just going
7 to object to the form. I think
8 you're getting outside the scope
9 of the deposition.
10 And also, you know, I've
11 given you some leeway just in
12 terms of establishing his
13 background, but this is really
14 getting outside the discovery
15 order as well.
16 You're asking him about
17 pricing negotiations involving API
18 for R&D not commercialized in
19 Europe, and the focus of the
20 deposition really needs to stay on
21 the commercialized product at
22 issue in this litigation which is
23 in the U.S.
24 So that's my objection, and

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1 I'll keep making it. But, you
2 know.
3 MR. STANOCH: I'm going to
4 ask -- I'm going to ask your
5 procurement witness how he
6 procured API from vendors that
7 Teva used to ultimately develop
8 the products that are at issue in
9 this case.
10 But I hear your -- I hear
11 your objections. It's noted,
12 counsel.
13 BY MR. STANOCH:
14 Q. Go ahead, Mr. Nassall. Do
15 you need me to repeat the question?
16 A. Yes, that would be nice.
17 MR. STANOCH: Madam court
18 reporter, could you read back the
19 question please.
20 (Whereupon, the court
21 reporter read back the requested
22 portion of testimony.)
23 MS. LOCKARD: Reiterate my
24 objection. Outside the scope of

Page 51

1 the deposition and outside the
2 scope of the discovery order.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
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11 [REDACTED]
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6 [REDACTED]
7 Q. Right. And -- okay. I
8 mean, all else being equal with API from
9 competing potential suppliers, I mean
10 price is going to be one of the
11 significant differentiators, right?
12 A. It is one of many
13 differentiators.
14 Q. Is it one of the -- is it
15 one of the more important
16 differentiators?
17 A. Well, for a generic
18 pharmaceutical company, it's, of course,
19 an important one. It's definitely not
20 the most important one. And it's
21 difficult to rank it. That's also why
22 the decisions are usually not taken --
23 Q. Are you able --
24 A. -- lightly.

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1 Sorry.
2 Q. No, I apologize. I thought
3 you were done, sir. Are you finished?
4 A. Yes.
5 Q. Are you able to say what the
6 most important factor is when Teva is
7 sourcing API for commercial product?
8 A. It's -- it varies from
9 product to product, from project to
10 project.
11 I mean the overarching
12 scheme I would say is that the API needs
13 to comply with the current rules and
14 regulations and current GMP.
15 Q. How about patient safety, is
16 that an important factor in sourcing API?
17 A. Patient safety is --
18 MS. LOCKARD: Objection.
19 Vague.
20 THE WITNESS: Sorry?
21 MS. LOCKARD: I said
22 objection to form. Vague.
23 THE WITNESS: So patient
24 safety is something quality team

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1 usually needs to weigh in. It is
2 an important factor. But it also
3 always needs to be -- you know,
4 you need to weight it overall.
5 BY MR. STANOCH:
6 Q. In your view then, is
7 patient safety not the most important
8 factor in an API that Teva sources?
9 MS. LOCKARD: Objection.
10 Vague.
11 THE WITNESS: As I said
12 before, it is one of the important
13 factors.
14 BY MR. STANOCH:
15 Q. But not the most important?
16 MS. LOCKARD: Objection.
17 Vague. Asked and answered.
18 THE WITNESS: As I said
19 before, it's important factor.
20 BY MR. STANOCH:
21 Q. You can't rank for me the
22 important factors that Teva considers
23 when sourcing API, right?
24 A. This is one of the tasks we

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1 always try doing. There is no way of
2 ranking the factors. It really is
3 depending on the specific product and the
4 projects. So there's no ranking.
5 Q. What factor is more
6 important than patient safety to Teva in
7 sourcing API?
8 MS. LOCKARD: Objection.
9 Vague.
10 THE WITNESS: As I said
11 before, it is -- it is an
12 important factor. No doubts about
13 that.
14 Patient safety as well
15 covers, you know, drug
16 availability, for example. So it
17 all needs to be taken into
18 account.
19 As I mentioned before, it
20 all starts that with whichever API
21 we are considering procuring and
22 using for one of our products.
23 The current GMP is a must. And
24 after that, it's all evaluating

Page 62	Page 64
<p>1 the overall picture of the API, 2 and as there is quality involved, 3 they will weigh in when it comes 4 to patient safety. 5 BY MR. STANOCH: 6 Q. And you in your procurement 7 role, I think you've said this earlier, 8 you never had any role in evaluating the 9 quality aspect of API, right? 10 A. I was not responsible to 11 rule on the quality aspect of the API. 12 Q. Right. And you were not 13 responsible for ruling on the patient 14 safety effects of API that Teva was 15 sourcing, correct? 16 MS. LOCKARD: Objection. 17 Vague. 18 THE WITNESS: So for this -- 19 the people from quality 20 department. There are also other 21 departments in toxicology, 22 pharmacovigilance, who have, like 23 a veto right in case a 24 manufacturer is suggested which</p>	<p>1 We have to take it into consideration. 2 But it's all in direct communication with 3 those departments. 4 Q. Those being quality 5 assurance and quality compliance. Any 6 others? 7 A. Yeah, pharmacovigilance 8 which is part of that. 9 Q. You mentioned toxicology, 10 right? 11 A. Yes, which is also part of 12 that. 13 Q. Right. Any others? 14 A. I would refer to all of that 15 on the quality. 16 Q. Understood. 17 You are familiar with the 18 entity Zhejiang Huahai Pharmaceutical, 19 right? 20 A. I know the company, yes. 21 Q. Right. And is it okay if we 22 call them ZHP today? 23 A. That's fine. 24 Q. And you understand that one</p>
Page 63	Page 65
<p>1 they don't consider being good 2 enough. So this is another 3 department. 4 BY MR. STANOCH: 5 Q. Right. The impact on 6 patient safety, that was not an ultimate 7 responsibility on you and your 8 procurement department, it was on other 9 departments within Teva, correct? 10 MS. LOCKARD: Objection to 11 form. 12 THE WITNESS: Well, it's 13 something which procurement needs 14 to take into consideration. But 15 the final judgment on that is 16 another department. 17 BY MR. STANOCH: 18 Q. Right. Got it. 19 So patient safety and API 20 sourcing is something you and your 21 sourcing department should take into 22 consideration, but don't have the final 23 say on it? 24 A. Well, it's not only issue.</p>	<p>1 of the main issues in this litigation 2 that we're here for this deposition today 3 is about valsartan API that Teva and 4 others sourced from ZHP, right? 5 A. I do understand, yes. 6 Q. When did you roughly first 7 have professional dealings with ZHP? 8 A. My first dealings with ZHP 9 should have been in 2008 when I was 10 staying in Shanghai. 11 Q. Right. I'm just looking at 12 your resumé. That's when you were chief 13 representative of ratiopharm Shanghai, 14 correct? 15 A. Correct. 16 Q. And I take it ZHP was one of 17 the potential API suppliers that you 18 would evaluate at the time for API for 19 ratiopharm, yes? 20 A. At that time that was still 21 the time when ratiopharm was not part of 22 Teva. So ratiopharm still was mainly 23 in-licensing finished product from 24 finished product manufacturers.</p>

<p style="text-align: right;">Page 66</p> <p>1 Q. I see.</p> <p>2 A. And there were only very few</p> <p>3 projects where we were looking for API.</p> <p>4 So there were some first contacts, but if</p> <p>5 I recall it correctly at that time,</p> <p>6 ratiopharm was not yet buying API</p> <p>7 directly from ZHP.</p> <p>8 Q. Was ratiopharm engaging in</p> <p>9 any licensing agreements with ZHP for</p> <p>10 finished dose products while you were</p> <p>11 chief representative at Shanghai?</p> <p>12 A. No, we did not.</p> <p>13 Q. Okay. And then when your</p> <p>14 employer formally became Teva in</p> <p>15 January -- or January 2011 is when you</p> <p>16 were R&D API sourcing at Teva, right?</p> <p>17 A. Right.</p> <p>18 Q. And so from that time, that</p> <p>19 role, from January 2011 to May 2014, did</p> <p>20 you have any dealings with ZHP?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And were you</p> <p>23 evaluating API from ZHP for Teva products</p> <p>24 at that time?</p>	<p style="text-align: right;">Page 68</p> <p>1 product R&D.</p> <p>2 Q. I see.</p> <p>3 Do you recall any</p> <p>4 discussions you had with ZHP regarding</p> <p>5 any valsartan API while you were director</p> <p>6 Europe R&D from January 2011 to May 2014?</p> <p>7 A. So that would have been for</p> <p>8 our R&D of any finished dosage form</p> <p>9 valsartan. I cannot recall that we had</p> <p>10 discussions on that.</p> <p>11 Q. Do you recall if Teva had a</p> <p>12 finished dose valsartan while you were in</p> <p>13 the director Europe R&D sourcing</p> <p>14 position, in commercialized finished dose</p> <p>15 valsartan?</p> <p>16 A. As far as I recall, Teva had</p> <p>17 valsartan, yes.</p> <p>18 Q. Do you recall during your</p> <p>19 time as director of Europe API sourcing</p> <p>20 from whom Teva was sourcing API for its</p> <p>21 finished dose valsartan?</p> <p>22 A. For the commercial product,</p> <p>23 you mean?</p> <p>24 Q. Yes, correct.</p>
<p style="text-align: right;">Page 67</p> <p>1 A. So I can't recall on, you</p> <p>2 know, at which exact point of time we did</p> <p>3 or did not. There were for sure regular</p> <p>4 discussions with ZHP, but whether it got</p> <p>5 to a point that we really evaluated the</p> <p>6 API or if it was just discussions, that I</p> <p>7 can't recall anymore.</p> <p>8 And for Teva, I do recall</p> <p>9 that ZHP, their development of APIs was</p> <p>10 usually a little bit too late for Teva's</p> <p>11 finished dosage form development.</p> <p>12 Q. Could you just explain what</p> <p>13 that means?</p> <p>14 A. So when Teva started the</p> <p>15 development of the finished product, that</p> <p>16 used to happen at a very early stage when</p> <p>17 sometimes just the originator launched</p> <p>18 sometimes the product.</p> <p>19 So at that time there were</p> <p>20 only very few API manufacturers already</p> <p>21 offering or working on the relevant API.</p> <p>22 And ZHP usually started development of</p> <p>23 the API just a little too late so that we</p> <p>24 could consider them in our finished</p>	<p style="text-align: right;">Page 69</p> <p>1 A. I mean I do know now.</p> <p>2 But at that time, I don't</p> <p>3 think that I knew.</p> <p>4 Q. And -- go ahead. Go ahead.</p> <p>5 Were you done, sir, I'm sorry?</p> <p>6 A. Yeah, I'm done. Sorry.</p> <p>7 Q. All right. And maybe we can</p> <p>8 just set up a little bit of a timeline.</p> <p>9 That's what we all understand now, right?</p> <p>10 I mean you understand that Teva had --</p> <p>11 was manufacturing, among other places,</p> <p>12 finished dose valsartan product,</p> <p>13 commercial market at the Jerusalem</p> <p>14 facility. Do you understand that?</p> <p>15 A. Yes, Jerusalem was one of</p> <p>16 the manufacturing sites at Teva, right.</p> <p>17 Q. You understand that the</p> <p>18 Jerusalem facility was sourcing API from</p> <p>19 Mylan for that finished dose valsartan,</p> <p>20 right?</p> <p>21 A. Jerusalem, yes, was sourcing</p> <p>22 from Mylan. Right.</p> <p>23 Q. And then there was also,</p> <p>24 among others, a Malta facility which Teva</p>

<p style="text-align: right;">Page 70</p> <p>1 acquired through an Actavis acquisition, 2 right? 3 A. The Actavis facility on 4 Malta was also manufacturing valsartan. 5 Q. Right. And that Malta 6 facility was sourcing valsartan API from 7 ZHP, correct? 8 A. Actavis Malta facility was 9 using ZHP valsartan. 10 Q. And to your knowledge, as it 11 stands now, was Teva sourcing valsartan 12 API from Mylan for any other facility 13 besides the Jerusalem facility? 14 A. Yes. But this was then not 15 for the U.S. markets. 16 Q. Right. There might have 17 been one or more other facilities 18 purchasing valsartan API from Mylan, but 19 they were making finished dose valsartan 20 product for non-U.S. markets, correct? 21 A. That is correct. 22 Q. To your knowledge, as it 23 stands today, were there other Teva 24 facilities besides the Malta Actavis</p>	<p style="text-align: right;">Page 72</p> <p>1 then there was no written agreement 2 between the Actavis Malta facility and 3 ZHP. But they used ZHP and the agreement 4 usually was based on purchase orders. 5 Q. Did you or your department 6 have any role in Teva's continued 7 procurement of valsartan API from ZHP for 8 the Malta facility, once the facility 9 became part of Teva? 10 A. Once Teva acquired Actavis, 11 during the integration, so there was a -- 12 there is a global procurement team which 13 I'm part of, and also local procurement 14 team at the end as part of global 15 procurement. 16 But what we did is, you 17 know, integrating the two different 18 procurements and then handle it the same 19 way we did it in Teva. 20 So for -- for the strategic 21 suppliers, the important products, then 22 there was always some kind of involvement 23 of the global procurement team. 24 Q. Got it. Was ZHP considered</p>
<p style="text-align: right;">Page 71</p> <p>1 facility that was sourcing valsartan API 2 from ZHP? 3 A. And again, yes, there were 4 other Teva facilities sourcing from ZHP. 5 Again, it was not for the U.S. market. 6 Q. Right. The only facility 7 that you're aware of that was sourcing 8 valsartan API from ZHP for the U.S. 9 market was the Malta Actavis facility, 10 right? 11 A. That's the only one I'm 12 aware of, yes. 13 Q. And with that, the Malta 14 facility -- I'll call it the Malta 15 facility, is that okay? 16 A. That's fine. 17 Q. With the Malta facility, my 18 understanding, you can correct me if I'm 19 wrong, my understanding since Teva 20 acquired that facility, there was already 21 a supply arrangement in place between the 22 Malta facility and ZHP for the valsartan 23 API, right? 24 A. If I recall that correctly,</p>	<p style="text-align: right;">Page 73</p> <p>1 a strategic supplier of Teva while you 2 were director global API category 3 strategy? 4 A. I cannot say for sure that 5 they have been considered from the very 6 start. But ZHP turned out to be one of 7 the bigger suppliers for Actavis. So 8 then after the acquisition, they also 9 became an important supplier for Teva. 10 More important than they were before. 11 Q. And do you have a sense of 12 how much of the API that Teva sourced 13 from ZHP, what percentage of either 14 unique APIs or overall volume ZHP 15 represented for Teva? 16 A. That's something we would 17 need to check in details and the 18 percentages are always difficult because 19 there are quantities, there is value. 20 So -- also the importance of 21 a supplier is not always defined by the 22 spend of money which we have with them. 23 But it's also defined by what the 24 finished product is, it goes into, and</p>

<p style="text-align: right;">Page 74</p> <p>1 how important that is for the specific 2 market in which it is being sold. 3 But taking all of that 4 together, then Huahai became one -- so 5 ZHP became one, one of our more important 6 manufacturers. 7 Q. Prior to 2018, would you say 8 that ZHP provided the most API to Teva 9 for generic products? 10 A. So besides the fact that, 11 you know, I cannot be 100 percent sure 12 without checking the numbers, but I'm 13 pretty sure that they were not the 14 biggest supplier of API for Teva. 15 Q. Who was, if you recall? 16 A. I really don't recall 17 especially at that time. That's 18 something we would need to -- 19 Q. Sure. And what type of 20 document would you look at to determine 21 the answer to that question? 22 A. We would need to dig into 23 historical spend data. 24 Q. Is there any sort of summary</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. Was it the top five? 2 A. I don't recall, but I would 3 say that in 2018 they were not top five. 4 Q. Do you recall them ever 5 being a top five? 6 A. I really can't say for sure 7 now. 8 MS. LOCKARD: David, if -- 9 when you get to a good transition 10 point, let's go ahead and take a 11 break. We've been going over an 12 hour please. 13 MR. STANOCH: That's fine. 14 We can take a break now. Let's go 15 off the record. 16 THE VIDEOGRAPHER: The time 17 right now is 1:18 p.m. We're off 18 the record. 19 (Short break.) 20 THE VIDEOGRAPHER: The time 21 right now is 1:28 p.m. We're back 22 on the record. 23 BY MR. STANOCH: 24 Q. Mr. Nassall, just yes or no,</p>
<p style="text-align: right;">Page 75</p> <p>1 reports that were regularly maintained 2 that would, you know, top line summarize 3 this type of information in terms of 4 biggest supplier of API generic? 5 MS. LOCKARD: Objection. 6 Form. Vague. 7 BY MR. STANOCH: 8 Q. I'm looking, sir, if you 9 have any more specific documents or data 10 besides spend data that we could look at 11 to answer these questions. That's all. 12 Can you think of anything? 13 A. Not right now. I mean -- 14 Q. Do you recall, even if you 15 don't know the name, do you recall, you 16 know, documents in the ordinary course of 17 your job that would break out which 18 suppliers represented the largest share 19 in dollars or volume of API for generic 20 products? 21 A. So right now, I don't 22 recall. What I do recall is at that time 23 ZHP -- and also up to now, ZHP never was 24 the biggest supplier.</p>	<p style="text-align: right;">Page 77</p> <p>1 did you speak with your counsel during 2 the break? 3 A. Yes, I shortly spoke. 4 Q. Okay. Are you familiar with 5 a Sonia Costi, C-O-S-T-I? 6 A. I do recall the name. She 7 was one of the R&D sourcing members a 8 while back. 9 Q. How about Pnina, P-N-I-N-A, 10 Weitz, W-E-I-T-Z? 11 A. I do recall her, she was my 12 manager. 13 Q. Okay. Manager in R&D 14 sourcing? 15 A. Yes. During R&D sourcing. 16 Q. How about Birgit Schnitter, 17 S-C-H-N-I-T-T-E-R? 18 A. Birgit was a team member of 19 R&D sourcing and for certain periods part 20 of my team reporting to me. 21 Q. How about a Gili Oshri, 22 O-S-H-R-I? Gili is G-I-L-I. 23 A. Gili was also part of the 24 R&D sourcing. Not reporting to me, but a</p>

<p style="text-align: right;">Page 78</p> <p>1 team member also reporting to Pnina. 2 Q. Who was Inbal, I-N-B-A-L, 3 Kan-Tor, K-A-N hyphen T-O-R? 4 A. Inbal, if I recall 5 correctly, was part of the commercial API 6 category. And I'm not sure if she was 7 always reporting to me in that function, 8 but for sure again for a certain period 9 of time. 10 Q. Commercial API sourcing, 11 right? 12 A. Yes. 13 Q. And how about Lina, L-I-N-A, 14 Cogan, C-O-G-A-N? 15 A. I don't recall the name. 16 Give me a second. 17 Q. Sure. No problem. 18 A. I'm not totally sure if she 19 was part of the R&D sourcing. But I 20 think she was part more again of the 21 commercial procurement. 22 Q. And how about Andreja 23 Schmitz, A-N-D-R-E-J-A, S-C-H-M-I-T-Z? 24 A. I do recall that name. She</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Thank you for that. Excuse 2 me. 3 How about Walton Wang? I 4 misspoke, I had a couple more names, sir, 5 sorry about that. Then we'll move on. I 6 promise, it's not a memory test of names. 7 Walton Wang, sir. 8 A. No problem. That's an easy 9 one. Walton is still part of Teva. He 10 is in the China procurement team. He was 11 for most of the time responsible for the 12 R&D sourcing of API. Right now I think 13 as well still with R&D. 14 Q. Did he have any -- okay. 15 Sorry. 16 A. No, no. Strike that. Go 17 ahead. 18 Q. Did Mr. Wang have any 19 responsibilities to your knowledge for 20 auditing potential API suppliers of Teva? 21 A. No. Mr. Wang was never an 22 official auditor, neither for ratiopharm, 23 nor for Teva. 24 Q. Who is Mr. Pan Lin?</p>
<p style="text-align: right;">Page 79</p> <p>1 has been my manager since I was in 2 commercial procurement. So from 2014 3 until now. 4 Q. Is Ms. Schmitz still with 5 Teva? 6 A. Yes, she is. 7 Q. And how about Joerg Fluch, 8 J-O-E-R-G, F-L-U-C-H? 9 A. He is still part of Teva. 10 And for certain period of time he was 11 also part of my team. Right now he's not 12 anymore. 13 Q. Okay. When you worked with 14 him, was he with you in commercial API 15 procurement? 16 A. Yes. 17 Q. And one more name for now, 18 sir. Gervan Klooster, G-E-R-V-A-N, 19 K-L-O-O-S-T-E-R? 20 A. Okay. Gervan was always 21 part of the commercial API team. Certain 22 period he was part of my team. He is 23 still with Teva, but not in my team 24 anymore.</p>	<p style="text-align: right;">Page 81</p> <p>1 A. Mr. Pan Lin also part of the 2 Teva China team. He is an official 3 auditor for quality audits in Teva. 4 Q. And could you just describe 5 for me generally from your perspective, 6 what the official auditors who conduct 7 the quality audits on behalf of Teva, 8 what are their responsibilities? 9 A. Obviously for the details, 10 you should probably directly ask the 11 quality audit team. 12 From what I do know is they 13 inspect the manufacturers or audit the 14 manufacturers, having a look at 15 production, documentation, the labs, and 16 see if this is all in accordance with 17 cGMP and all other rules and regulations 18 which are there from Teva authorities, 19 but also according to what Teva wants to 20 set as a standard for us. 21 Q. And we'll just say from your 22 time in commercial API sourcing, so 23 that's May 2014 or thereabouts forward, 24 you and your department of procurement,</p>

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1 you had no role in auditing API
2 suppliers, right?
3 A. The procurement team had no
4 role in any of quality audits. We might
5 have initiated them and helped organizing
6 them. But that's it.
7 Q. Right. And you can correct
8 me if I'm wrong, but given that you
9 were -- you and your department in
10 procurement were sort of the
11 supplier-facing function, you may -- you
12 may have communications about logistics
13 and arranging audits, but you weren't
14 responsible in any way for actually
15 conducting the audits. Is that fair?
16 A. It's fair to say we never
17 conducted any of the quality audits.
18 Q. If you know, when did
19 Mylan -- strike that.
20 When did -- if you know,
21 when did Teva begin to source valsartan
22 API from Mylan?
23 A. I cannot recall when Teva
24 started sourcing valsartan from Mylan.

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1 Q. Did you have any role in,
2 personally, in Teva's choosing Mylan to
3 supply valsartan API to the Teva
4 Jerusalem facility?
5 A. If I recall it correctly,
6 then this was done before I was part of
7 the team.
8 Q. Right. That was going --
9 that was where I was going to go, sir.
10 My understanding was that
11 Teva would have began purchasing
12 valsartan API from Mylan for the
13 Jerusalem facility prior to your
14 involvement.
15 A. As far as I recall, yes.
16 Q. And prior to 2018, do you --
17 did you have any interactions that you
18 recall with Mylan concerning the sourcing
19 of valsartan API for the Jerusalem
20 facility?
21 A. I would say -- I mean we had
22 regular discussions with most of our
23 manufacturers, especially like Mylan and
24 ZHP. There were also some personal

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1 meetings, and we discussed for sure a lot
2 of API during those meetings. I cannot
3 recall a specific topic on valsartan with
4 Mylan before 2018.
5 Q. Would you have been the
6 person at Teva who would have discussed
7 the procurement of valsartan API from
8 Mylan for the Jerusalem facility?
9 A. I mean if it had been after
10 I became -- then I would say this would
11 have been when I would have been
12 involved, yes.
13 Q. Now, again focusing now in
14 director global API category, May 2014
15 forward, okay, just to help orient you?
16 A. Okay.
17 Q. Were there specific members
18 in your group assigned to specific API
19 suppliers to liaise with?
20 A. So at the beginning, our
21 focus was on the products. And there was
22 a responsibility within my team and the
23 other global procurement teams, that
24 someone was responsible for certain APIs.

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1 Then very early we also
2 started having responsibilities to
3 certain API manufacturers. And then it
4 gradually changed over time, that
5 responsibility was -- you know, at the
6 beginning it was more important that we
7 have someone who was responsible for a
8 certain product. And then it more and
9 more moved towards responsibility with
10 API manufacturers.
11 Q. So starting in May 2014,
12 were there persons in global procurement
13 who were responsible for valsartan API?
14 A. As far as I recall, yes.
15 Q. Who do you recall were those
16 persons?
17 A. In 2014, I don't recall.
18 Q. How about going forward in
19 time from 2014, do you recall any of the
20 persons within procurement who had
21 responsibilities specifically for
22 valsartan API?
23 A. So I cannot tell you at
24 which date it officially started. But

<p style="text-align: right;">Page 86</p> <p>1 Ms. Inbal Kan-Tor, whom you mentioned 2 before, was at a certain period 3 responsible for valsartan. 4 Later on, Mr. Joerg Fluch 5 took over the responsibility for 6 valsartan. And as far as I can recall, 7 there was -- I'm really not sure, if you 8 have a document would showing me 9 something different -- but I would say 10 Ms. Inbal Kan-Tor and Joerg Fluch and 11 probably no one else. 12 Q. And then -- and you 13 mentioned at some point it may have 14 shifted and that responsibilities began 15 more focused on API manufacturer versus a 16 specific API product. 17 Do you recall whether there 18 were specific people in procurement who 19 were responsible for interactions with 20 ZHP and Mylan for commercial API? 21 A. Well, yes, I do recall. 22 Q. Okay. And if you can please 23 list them both, you know, for me? 24 A. Mm-hmm.</p>	<p style="text-align: right;">Page 88</p> <p>1 product responsible one was directly 2 dealing with that, with the relevant 3 manufacturer. 4 Those for the product 5 specific responsible persons, they also 6 were thinking of, you know, several Teva 7 sites, buying the same API. They were 8 trying to come up with ideas how to do 9 that in the future, do we want to change 10 something. 11 But then if it came to -- to 12 any longer or bigger discussions with 13 more than just one API, then these 14 supplier relationship managers, let's 15 say, took over. And usually, you know, 16 the biggest APIs which we're buying from 17 these suppliers also defined who became 18 responsible for the manufacturer. 19 MR. STANOCH: Stand by for 20 the next exhibit, sir. Strike 21 that. 22 BY MR. STANOCH: 23 Q. I know it was a while ago in 24 time, sir, but do you recall any issues</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Thank you. 2 A. If I remember correctly, 3 then both for Mylan and for ZHP it was at 4 one point of time Dalia Reuven. 5 Q. Could you spell that last 6 name? 7 A. The last name is 8 R-E-U-V-E-N. 9 Q. Thank you. 10 A. But if I also recall 11 correctly, she left the team early 2018. 12 And the responsibility again, if I recall 13 it correctly for both Mylan and ZHP, went 14 on to Joerg Fluch. 15 Q. And for both of those 16 persons, the responsibilities of Mylan 17 and ZHP would have encompassed the 18 sourcing of valsartan API, right? 19 A. Well, there was -- as I 20 mentioned, there were also still 21 responsibilities on the API and then also 22 on the suppliers, and it was always, if 23 there was a specific topic, day-to-day 24 business on the product, then usually the</p>	<p style="text-align: right;">Page 89</p> <p>1 with Teva's sourcing of valsartan API 2 from ZHP back in 2011? 3 MS. LOCKARD: Objection to 4 form. Vague. 5 THE WITNESS: In 2011? 6 BY MR. STANOCH: 7 Q. Yes. 8 A. Did I hear that correct? 9 Q. Yes. Correct. 10 A. So I think -- first of all, 11 this was a time in 2011 that was shortly 12 after Teva acquired ratiopharm and I was 13 part of R&D sourcing. 14 So I would not be involved 15 in any of the commercial aspects. And it 16 also cannot be anything related directly 17 to the topic we are talking about today. 18 I mean, over such long 19 period of time there can be discussions 20 on -- so no, I don't recall. 21 MR. STANOCH: Stand by. 22 (Document marked for 23 identification as Exhibit 24 Teva-317.)</p>

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1 MR. STANOCH: I'm marking
2 Teva 317 for the record. It's
3 Bates ending 5126.
4 BY MR. STANOCH:
5 Q. Mr. Nassall, just let me
6 know when you can access that exhibit.
7 A. Okay. Reloading. Opening.
8 Okay, I see that document now.

[REDACTED]

Page 91

[REDACTED]

Page 92

[REDACTED]

Page 93

[REDACTED]

Page 94

[REDACTED]

Page 96

[REDACTED]

16 Q. I'm going to share my screen
17 for a prior marked exhibit. If you can
18 see my screen. Can you see my screen,
19 sir?
20 A. No.
21 Q. Well, stand by. I'm going
22 to -- let me try that again. Sorry about
23 that. Stand by.
24 How about now?

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[REDACTED]

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1 A. I can see parts of it. Yes.
2 Q. You see it's --
3 MR. STANOCH: For the
4 record, this is previously marked
5 Teva 270.
6 BY MR. STANOCH:
[REDACTED]

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[REDACTED]

Page 100

[REDACTED]

Page 99

[REDACTED]

Page 101

[REDACTED]

Page 102

[REDACTED]

Page 104

[REDACTED]

4 MR. STANOCH: I'm going to
5 mark the next exhibit, sir.
6 Teva 318.
7 Stand by. For the record it
8 will be Bates number ending
9 187585.
10 (Document marked for
11 identification as Exhibit
12 Teva-318.)
13 BY MR. STANOCH:
14 Q. Let me know, sir, when you
15 can access that document?
16 A. 318. Yes.
17 Q. This is --
18 A. I see it.

[REDACTED]

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[REDACTED]

Page 105

[REDACTED]

Page 106

[REDACTED]

Page 108

[REDACTED]

Page 107

[REDACTED]

Page 109

[REDACTED]

<p>Page 110</p> <p>[REDACTED]</p>	<p>Page 112</p> <p>[REDACTED]</p>
<p>Page 111</p> <p>[REDACTED]</p>	<p>Page 113</p> <p>[REDACTED]</p>

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■ [REDACTED]

4 BY MR. STANOCH:

5 Q. Mm-hmm. You considered ZHP

6 to be a very cost competitive supplier of

7 API, didn't you?

8 A. This is, I would say,

9 depending on the product. They were not

10 always competitive on all the APIs which

11 they were offering. But for some, they

12 also were competitive.

13 Q. Right.

14 A. But the main thing being is

15 they were also really a reliable and good

16 supplier.

17 Q. Mm-hmm. Mm-hmm.

18 Well, in terms of cost

19 effectiveness, for valsartan API, you

20 know, because you are aware of the

21 pricing from procurement of -- generally,

22 right?

23 A. In general, I'm aware of

24 pricing.

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1 Q. Right. And ZHP's prices for

2 valsartan API was very competitive,

3 wasn't it?

4 A. Again, I mean this changed

5 over time as prices change and processes

6 change.

7 In general, ZHP for

8 valsartan was not necessarily the

9 cheapest. But they were competitive and

10 competitive they have been price-wise and

11 quality-wise.

12 Q. ZHP's valsartan API was

13 cheaper than a lot of competing API

14 suppliers of valsartan API, wasn't it?

15 A. Again, that depends on at

16 which exact time you are asking. Prices

17 change. Often ZHP for valsartan was

18 competitive, not necessarily always the

19 cheapest but competitive with respect to

20 prices and quality.

21 Q. Let's talk before 2018.

22 ZHP was one of the cheapest

23 options for valsartan API to Teva

24 systems, correct?

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1 A. I cannot fully recall. But

2 I can only say the same, again. ZHP for

3 valsartan was at many points of time

4 competitive, and this competitive is not

5 only with respect to price.

6 And again, they were not

7 always the cheapest. They were

8 competitive with respect to the price and

9 to the quality of the product.

10 Q. Mm-hmm. And we'll look at

11 specific pricing later today for sure,

12 Mr. Nassall, and examples of it for ZHP's

13 valsartan's API prices.

14 But -- but you would

15 certainly agree though that ZHP's prices

16 for valsartan API prior to 2018 was among

17 the cheapest that Teva had for its

18 system, correct?

19 MS. LOCKARD: Objection.

20 Asked and answered.

21 THE WITNESS: As I said

22 before, Huahai was competitive

23 with respect to price and quality,

24 and I would not recall if they had

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1 been always the cheapest. I would

2 say they were not. But they were

3 always in the competitive range.

4 BY MR. STANOCH:

5 Q. Whoever sold cheaper

6 valsartan API to Teva prior to 2018?

7 A. I cannot recall.

8 Q. Right. So you can't recall

9 whether ZHP was the cheapest valsartan

10 API, can you?

11 A. I cannot recall at, you

12 know, every specific point in time who

13 was the cheapest offer. And I'm pretty

14 sure there were cheaper offers, because

15 we also -- I would not be able to tell

16 you the name, but we didn't -- most of

17 the cases when we -- when we look for

18 prices for certain API, there is always

19 someone producing this API for

20 nonregulated markets and you get offers

21 of this API and they usually are the

22 cheapest. So I'm pretty sure that they

23 have been also cheaper than Huahai. But

24 this is nothing we can use them in our

<p style="text-align: right;">Page 118</p> <p>1 production for the U.S. or for Europe. 2 Q. Right. That's a good point, 3 sir. Let's focus on valsartan API 4 intended for finished dose in the U.S. 5 market. 6 ZHP's valsartan API was 7 among the cheapest available to Teva for 8 that product, correct? 9 A. So again, I don't recall 10 exactly how the market situation before 11 2018 was. And I don't recall who was the 12 cheapest. But I can tell you that ZHP 13 for sure was a competitive manufacturer 14 for valsartan for the U.S. market. And 15 this was with respect to price and 16 quality. 17 Q. Mm-hmm. Well, Teva never 18 changed its sourcing for valsartan API 19 from ZHP for the Malta facility prior to 20 2018, did it? 21 A. Sorry, again. 22 Q. Prior to 2018, Teva did not 23 change its valsartan API supplier for the 24 Malta facility from ZHP, correct?</p>	<p style="text-align: right;">Page 120</p> <p>1 evaluating the overall situation of these 2 products and then coming up with a 3 decision with which one you keep. 4 And only then -- then 5 there's also an integration of which of 6 the manufacturing sites you keep and 7 maybe, you know, after such an 8 acquisition you have two big 9 manufacturing capabilities. 10 And then there were also 11 many examples of a manufacturing of a 12 finished dosage form shifted to another 13 site. And only then you start evaluating 14 do we now need, you know, to improve 15 something else. 16 So ZHP API came with the 17 acquisition of Actavis. And then if you 18 want to do a real material change and 19 introduce a new API source, then you also 20 need to evaluate -- price is not the only 21 thing there. But even if there had been 22 a cheaper source compared to ZHP, then 23 the question is how big is the price 24 difference and which other pros and cons</p>
<p style="text-align: right;">Page 119</p> <p>1 A. So there -- you know, first 2 of all, this Malta manufacturing site 3 came with the acquisition of Actavis. 4 They had a manufacturer for the API for 5 this product which, if I recall 6 correctly, was ZHP. 7 Then the integration of a 8 company like Actavis requires already 9 quite an effort, capacity, and energy. 10 So the first thing what you 11 do in such -- or after such an 12 acquisition and during the integration 13 phase, is that you need to harmonize the 14 products. Because of cost there were 15 some finished products which Teva 16 produced before the acquisition and then 17 Actavis had the same product, and then 18 you need to come up with a decision which 19 of the two products you keep at the 20 market or maybe both. 21 And for that we didn't -- 22 this is not only procurement. This is 23 portfolio people. This is also 24 regulatory people, quality people,</p>	<p style="text-align: right;">Page 121</p> <p>1 come with the new API source for this 2 product. 3 So at the end, until 2018, 4 there was obviously not enough reasons to 5 introduce another new source, but that 6 does not necessarily mean that for the 7 whole time ZHP was the cheapest source. 8 Q. And you were director of 9 global API category strategy at Teva at 10 the time of the Actavis integration, 11 correct? 12 A. Yes, that's correct. 13 Q. And you never recommended 14 that the Malta facility switch valsartan 15 API suppliers away from ZHP, did you? 16 A. As far as I recall, we did 17 not recommend that. 18 Q. Right. And the Malta 19 facility continued to source valsartan 20 API from ZHP after the Actavis 21 integration, right? 22 A. That's correct. And that's 23 what you also usually do after an 24 acquisition. You are not moving</p>

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1 everything at the same time.
2 Q. Right. And then for the
3 years after the acquisition through the
4 recalls that began in 2018, Teva's Malta
5 facility continued to source the ZHP
6 valsartan API, right?
7 A. You mean after the topic
8 occurred in June 2018?
9 Q. Up to that point.
10 A. Up to that point. Up to
11 that point, as far as I recall, the
12 Actavis Malta facility continued
13 procuring valsartan for the U.S. market
14 from ZHP.
15 Q. Right. And then even after
16 the nitrosamine issue surfaced in the
17 summer of 2018, Teva was still looking
18 into continuing to source a valsartan API
19 from ZHP, isn't that right?
20 A. So the Actavis facility in
21 Malta for the U.S. stopped production for
22 the U.S. So there was no procuring of
23 valsartan from ZHP for the U.S. market.
24 And if I recall it correctly, there was

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1 also no other Teva site manufacturing
2 valsartan for the U.S. market anymore.
3 Q. Right. Well, the production
4 from the Malta facility was transferred
5 to the Dupnitsa facility, correct?
6 A. Dupnitsa is manufacturing
7 for the European market.
8 Q. And are they -- they are
9 manufacturing valsartan finished product
10 for the European market today, right?
11 A. Dupnitsa is also today
12 manufacturing for the European markets.
13 Q. Valsartan, correct?
14 A. Yeah, valsartan, sorry.
15 Q. Are they sourcing valsartan
16 API from ZHP?
17 A. Dupnitsa for the European
18 market is currently procuring valsartan
19 from ZHP.
20 Q. So -- so the same company
21 that goes back to 2011 with quality
22 issues that had all these nitrosamine
23 issues in 2018, to this day now, Teva is
24 sourcing valsartan API from ZHP for the

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1 European market?
2 MS. LOCKARD: Objection.
3 Form. Vague.
4 THE WITNESS: Sorry. Was
5 there a question? I missed it.
6 BY MR. STANOCH:
7 Q. Yes.
8 A. Could you repeat then?
9 Sorry.
10 Q. Sure.
11 So for the same ZHP that
12 we've seen Teva had valsartan API issues
13 with back to 2011, through the
14 nitrosamine issues in 2018, despite all
15 of that, today Teva is still sourcing
16 valsartan API from ZHP for the European
17 market?
18 MS. LOCKARD: Objection.
19 Form. Vague.
20 THE WITNESS: So first of
21 all, I would not say that this --
22 again, I did not see now what the
23 result was.
24 But from what I do recall in

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1 2011, this was at the end not a
2 big quality issue and it has
3 nothing to do with valsartan. It
4 was on another product.
5 The valsartan impurity topic
6 which happened in 2018, it turned
7 out at the end that it does not
8 only -- it did not only affect the
9 material coming from ZHP, but many
10 other API manufacturers.
11 And ZHP and also many of the
12 other valsartan manufacturers in
13 the meantime fixed the problem.
14 So there's no reason why we
15 could not continue buying for the
16 markets as long as they complied
17 with cGMP and the current
18 regulations on this product.
19 And this is what you usually
20 do. I mean, if there is an
21 impurity issue or any other
22 problem, you solve it so that you
23 can continue.
24 BY MR. STANOCH:

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1 Q. Would Teva be sourcing
2 valsartan API from ZHP for the U.S.
3 market but for the FDA import ban on ZHP?
4 MS. LOCKARD: Objection.
5 Calls for speculation.
6 THE WITNESS: So that I
7 could only wildly guess, because
8 the situation is what the
9 situation is.
10 Currently there's an import
11 ban. There's also warning letter,
12 so there is no way for us to
13 source valsartan for the U.S.
14 And Teva also completely
15 stopped marketing valsartan in the
16 U.S. This was a decision at least
17 not only because of the impurity
18 topic. The market situation in
19 the U.S. is in a way the currently
20 the position is that we don't sell
21 valsartan in the U.S.
22 In case Huahai would solve
23 the issue also in a way that it
24 complies with all current rules

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1 and regulations for the U.S., and
2 if they qualify, if our quality
3 team does an audit, then there is
4 no reason why not. And this is
5 theoretically and hypothetically,
6 to also procure from ZHP.
7 BY MR. STANOCH:
8 Q. Are you aware of any plans
9 within Teva to re-introduce finished dose
10 valsartan in the U.S. market?
11 A. Currently at this point of
12 time, I'm not aware of anything.
13 Q. And from a procurement
14 perspective, would ZHP be a potential API
15 supplier of valsartan if the regulatory
16 issues were cleared up?
17 MS. LOCKARD: Objection.
18 Calls for speculation.
19 THE WITNESS: This is
20 something at the end, our quality
21 department would need to judge on
22 the quality. Regulatory
23 department would need to judge on
24 documentation.

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1 So this would be full
2 involvement of everyone involved
3 in the sourcing process. And if
4 rules and regulations are kept and
5 if everything is according to
6 current GMP, then there would be a
7 decision which I cannot give you
8 right now in a hypothetical way.
9 BY MR. STANOCH:
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 BY MR. STANOCH:
14 Q. From your perspective as a
15 procurement professional, it would be a
16 competitive disadvantage to Teva if it
17 stopped sourcing API from ZHP; is that
18 right?
19 A. If you mean this competitive
20 with respect to -- again, it's the
21 overall package. They were competitive
22 with respect to the price. But they were
23 also competitive with their competitors
24 with respect to reliability, the security

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1 of supply, and the quality of the
2 products which they were supplying.
3 I definitely do not want to
4 say that they were only just the cheapest
5 available source. Overall, for many --
6 many examples, they should take
7 everything into consideration. They were
8 one of the best sources.
9 Q. Let's look -- let's look
10 at -- so your -- so with valsartan API,
11 would you say price is the only issue,
12 assuming all else equal?
13 A. Sorry, I don't understand.
14 Q. Sure.
15 Assuming everything with
16 quality, for competing with valsartan API
17 suppliers is the same, would price for
18 that valsartan API be the only issue?
19 A. If you say that quality wise
20 everything is the same, then there are a
21 lot of other factors, not only the price.
22 There are factors like reliability of
23 supply, security of supply, if you always
24 get delivered on time and in full.

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1 Q. So you never said that price
2 is the only issue for valsartan API?
3 A. I would not say that right
4 now.
5 Q. Have you ever said that?
6 A. Not that I can recall.
7 MR. STANOCH: Let's take a
8 look at the next exhibit. Teva
9 319. For the record, it's Bates
10 ending 108342.
11 (Document marked for
12 identification as Exhibit
13 Teva-319.)
14 BY MR. STANOCH:
15 Q. Let me know when you can
16 access that document, sir.
17 A. I'm sorry. 3 what? 19?
18 Q. 18, I believe it was.
19 A. 18. Sorry.
20 Q. No, I apologize. I
21 apologize. You were right. I was wrong
22 sir. I muddled the record.
23 Teva 319, please. It's
24 Bates ending 108342. My apologies.

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1 A. Yes.
2 Q. Are you there?
3 A. Yes.
[REDACTED]

Page 133

[REDACTED]

Page 134

[REDACTED]

Page 136

[REDACTED]

Page 135

[REDACTED]

Page 137

[REDACTED]

Page 138

[REDACTED]

Page 140

[REDACTED]

11 Q. Since the nitrosamine issues
12 that led to the recalls in 2018, have you
13 had any hesitancy in sourcing API from
14 ZHP?
15 A. Teva in general, it's going
16 the same process. We are evaluating --
17 and it depends on the product, and what
18 then the audit situation is, on the exact
19 manufacturing site of ZHP, what the
20 auditing situation is on the product
21 you're looking for.
22 And if then for this
23 specific product coming from this
24 specific site, if everything is according

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[REDACTED]

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1 to cGMP and if our audit team gives the
2 green light, then there's currently no
3 reason of not considering them.
4 Q. So today, you have no
5 hesitancy in dealing with ZHP for API,
6 notwithstanding all the nitrosamine
7 issues that occurred in 2018 and forward?
8 A. I would say that there's the
9 same hesitancy for -- for all the API
10 manufacturers, especially now after that
11 nitrosamine topic. Authorities are
12 asking for risk assessments for all
13 chemically manufactured API.
14 So there's a whole new set
15 of evaluation we need to do and this is
16 going to depend on who is the API
17 manufacturer.
18 Q. So there's nothing specific
19 in terms of how Teva's procurement has
20 changed when it comes to sourcing API
21 from ZHP after 2018?
22 A. Let me think. I mean, of
23 course now we ask all the questions
24 related to -- related to the nitrosamine

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1 topics and we are trying to be more
 2 cautious. But I would not say that it's
 3 in any special way different to ZHP than
 4 to other manufacturers as far as I recall
 5 that.

6 Q. Is Teva's procurement
 7 approach of API from ZHP any different
 8 today, other than asking about
 9 nitrosamines, than it was prior to 2018?

10 A. Well, I mean nitrosamine is
 11 the most prominent factor that changed
 12 since 2018. But there are constant
 13 changes in all rules and regulations.

14 There are also some -- some
 15 new questions we now ask after the
 16 experience of Covid last year. So I
 17 would not say that this is the only one.
 18 But this is maybe the most prominent
 19 change since 2018.

20 Q. Other than asking about
 21 nitrosamines and asking about Covid
 22 concerns, are there any other specifics
 23 you can describe for me as how Teva's
 24 procurement approach has changed with ZHP

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1 since the 2018 recalls?
 2 MS. LOCKARD: Objection.
 3 Asked and answered.

4 THE WITNESS: As I just
 5 mentioned, I mean all rules and
 6 regulations keep changing. And
 7 this is true for -- for all the
 8 health authorities which we are
 9 dealing with in each of the
 10 countries where we are selling
 11 products.

12 So I'm pretty sure that a
 13 lot has changed since 2018 and
 14 this is also always influencing
 15 our sourcing process in certain
 16 ways.

17 BY MR. STANOCH:
 18 Q. Do you trust ZHP today as
 19 much as you did prior to 2018?

20 MS. LOCKARD: Objection.
 21 Vague.

22 THE WITNESS: I trust that
 23 we are asking the right questions
 24 and that we are doing the right

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1 evaluation to, at the end, find
 2 the best source for -- for API.

3 BY MR. STANOCH:
 4 Q. Because in 2018, isn't it
 5 correct that ZHP made a number of
 6 statements about nitrosamines to Teva
 7 that turned out to be incorrect?

8 A. In 2018. So I guess you
 9 might have a document to help me remember
 10 that.

11 Right now I would say the
 12 whole -- the whole period starting end of
 13 June 2018 until the end of 2018, this was
 14 a developing story and the situation
 15 changed sometimes on a daily basis.

16 Also, what we knew and what
 17 the fact was -- were changed sometimes on
 18 a daily basis. The requests from health
 19 authorities were updated, maybe not on a
 20 daily basis, but they probably updated on
 21 a weekly basis. So I cannot recall if
 22 there -- if there was anything wrong.

23 But as I said, the overall
 24 situation was very dynamic. No, sorry.

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1 Q. You done?
 2 A. Yes.

3 Q. No, I just want to make sure
 4 because you --

5 A. Sorry.

6 Q. No. Thank you. No. It's
 7 fine.

8 And it's harder over the
 9 video. I appreciate your patience with
 10 it.

11 So I mean, we can look at
 12 specific examples, and we will, sir. But
 13 certainly you recall that there were
 14 times after June 2018 where ZHP would
 15 tell Teva something about nitrosamines
 16 and it would turn out that that was
 17 inaccurate, correct?

18 MS. LOCKARD: Objection.
 19 Vague.

20 THE WITNESS: Again, what I
 21 just said was it was a very
 22 dynamic situation. Some facts
 23 kept changing constantly. So I'm
 24 pretty sure that everyone, not

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1 only ZHP, potentially also Teva,
2 said something on any given day
3 which then a few days later might
4 have been seen as wrong as the
5 whole situation changed.
6 BY MR. STANOCH:
7 Q. You didn't want to lose ZHP
8 as an API supplier for Teva, did you?
9 A. Well, why would I want to
10 wish losing them, especially as we saw
11 that the impurity was -- it was nothing
12 which was only in ZHP products. I would
13 not have known to switch to -- with
14 valsartan.
15 Q. Right. There were a number
16 of other producers of valsartan API,
17 right?
18 A. Of course there are.
19 Q. Right. And today, Teva
20 sells a number of products that contain
21 valsartan throughout the world and they
22 source that API from multiple other
23 companies besides ZHP, right?
24 A. Yes. And we also did that

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1 already before.
2 Q. Right. And ZHP was a very
3 important source of API generally from
4 your perspective in procurement, isn't
5 that correct?
6 MS. LOCKARD: Objection.
7 Asked and answered.
8 THE WITNESS: ZHP was one of
9 the important manufacturers of API
10 for Teva. And there are also many
11 others.
12 BY MR. STANOCH:
13 Q. Right. And you as a
14 procurement officer at Teva, even after
15 the nitrosamine issues in 2018, you did
16 not want to lose ZHP as an API supplier
17 generally for Teva, did you?
18 MS. LOCKARD: Objection.
19 Asked and answered.
20 THE WITNESS: I would not
21 want to lose any of our API
22 manufacturers whom we currently
23 consider as the important ones.
24 And there are more than --

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1 than Huahai, and I don't wish to
2 lose any of those.
3 BY MR. STANOCH:
4 Q. Well, Teva changes API
5 suppliers from time to time for various
6 APIs, right?
7 A. Yes.
8 Q. But to this day, Teva is
9 still sourcing API from ZHP, right?
10 A. Yes, we are still sourcing
11 API from ZHP for several markets. We are
12 not sourcing API from ZHP for the U.S.
13 markets. And this is the same as what we
14 do with many API manufacturers.
15 Q. And, in fact, Teva is
16 sourcing a lot of API from ZHP to this
17 day, isn't that right?
18 A. ZHP is still one of the
19 important manufacturers from whom we
20 source many API. But there are also a
21 lot of other manufacturers from whom we
22 source a similar or even bigger amount of
23 API.
24 Q. Right. And you from a

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1 procurement perspective did not want to
2 lose ZHP as an API supplier even after
3 all the nitrosamine issues and recalls in
4 2018, correct?
5 MS. LOCKARD: Objection.
6 Asked and answered.
7 THE WITNESS: So especially
8 for those what we know in this
9 conversation or this session
10 called the important API
11 manufacturers, those are the ones
12 where we buy several API.
13 And I don't want to lose any
14 of them, because this would mean a
15 lot of material changes in a lot
16 of our manufacturing sites which
17 is -- would mean a lot of capacity
18 of what we can do, would be then
19 stuck in such a case.
20 And for all of our important
21 manufacturers, we always try and
22 hope that they can -- you know, if
23 there is an issue, that it can be
24 solved and that then we can

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1 continue doing business. And this
2 is not only for ZHP, but for all
3 of the important manufacturers.
4 BY MR. STANOCH:
5 Q. Well, Teva gets a very
6 competitive price from ZHP generally for
7 APIs, to this day, right?
8 A. I would tend to say, and I
9 believe that this is true, that Teva gets
10 a competitive price from all of its
11 manufacturers.
12 Q. Well, let's talk ZHP
13 specifically, sir.

[REDACTED]

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[REDACTED]

Page 152

[REDACTED]

20 Just a couple more questions
21 and we'll take a break, sir, if that's
22 okay.
23 In your view, it would hurt
24 Teva's bottom line if it stopped sourcing

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1 API from ZHP, correct?
2 MS. LOCKARD: Objection.
3 Form. Vague.
4 THE WITNESS: No. And I
5 also didn't understand. Sorry.
6 BY MR. STANOCH:
7 Q. Sure.
8 Teva sources very
9 competitive API from ZHP, right?
10 A. This is what we do and what
11 we also do from others, but, yeah.
12 Q. Right. Right. You try to,
13 but the ZHP pricing, it has a direct
14 impact on Teva's bottom line as a cost
15 for its finished dose products, right?
16 A. Well, I mean the price we
17 pay for an API is -- whoever the
18 manufacturer is, is directly affecting
19 the bottom line --
20 Q. Right. Of course. So if
21 ZHP's prices are low for an API, that's
22 good for Teva's profitability, correct?
23 A. Again, ZHP's price is
24 competitive, but it's also very

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1 competitive with many of our other
2 manufacturers. And it's not always the
3 cheapest.
4 And what I just said with
5 respect to that agreement, and I really
6 hope that we will have a look at it, what
7 it exactly says, this is meant so that we
8 can recover at least parts of the damages
9 and losses which we suffered through this
10 nitrosamine.
11 Q. You know that if Teva
12 stopped sourcing API from ZHP, it would
13 have to go to different API suppliers who
14 have higher prices, right?
15 MS. LOCKARD: Objection.
16 Speculation.
17 THE WITNESS: This depends
18 and is different from API to API.
19 By accident we just had a
20 comparison again, and I can tell
21 you that ZHP is definitely not the
22 cheapest available source for any
23 given API.
24 BY MR. STANOCH:

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1 Q. Well, we'll talk about that
2 a little more.
3 But you, from a procurement
4 perspective, did not want to lose ZHP as
5 an API supplier because of ZHP's
6 competitive pricing, right?
7 MS. LOCKARD: Objection.
8 Asked and answered.
9 THE WITNESS: We, in
10 procurement, always try not losing
11 any of our good and big and
12 reliable API suppliers who are
13 competitive with respect to price,
14 quality, reliability.
15 And there are many, and not
16 only ZHP's.
17 BY MR. STANOCH:
18 Q. Is ZHP a reliable supplier
19 after it cost Teva millions and millions
20 of dollars because of the nitrosamine
21 issues?
22 MS. LOCKARD: Objection.
23 Argumentative.
24 THE WITNESS: This is --

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1 for -- I mean this is always an
2 ongoing evaluation. And it's not
3 only my opinion which counts in
4 this case. And it keeps changing
5 and it also kept changing since
6 2018.
7 And if at the current stage
8 there would need to be a decision
9 of who can be an API source, then
10 again it would be a team effort of
11 quality, regulatory, manufacturing
12 people, and also procurement,
13 trying to assess the overall
14 situation.
15 BY MR. STANOCH:
16 Q. Do you consider ZHP --
17 sorry.
18 A. That's okay.
19 And then from -- I mean,
20 from the internal evaluation of the
21 current stage to us, it looks like the
22 nitrosamine situation, which was not --
23 not only hitting ZHP but many other
24 companies, currently the situation is

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1 under control. And if it fits to the
2 product, and, you know, with current GMP,
3 then ZHP also can be considered as a
4 reliable supplier.
5 Q. Do you consider ZHP to be a
6 reliable supplier today?
7 MS. LOCKARD: Objection.
8 Asked and answered.
9 THE WITNESS: Again, it's
10 not -- not only my opinion that
11 counts there. And it's a team
12 effort, if you take a decision
13 like this.
14 And it depend on the
15 specific situation. For example,
16 currently I would not say that ZHP
17 is a reliable supplier for
18 valsartan in the U.S.
19 But in many other cases,
20 depending on the API and the
21 overall situation, they can be
22 considered as a reliable supplier.
23 MR. STANOCH: Let's take
24 that break now, Mr. Nassall.

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1 Thank you.
2 THE WITNESS: Okay.
3 THE VIDEOGRAPHER: The time
4 right now is 3:03 p.m. We are off
5 the record.
6 (Short break.)
7 THE VIDEOGRAPHER: The time
8 right now is 3:16 p.m. We're back
9 on the record.
10 BY MR. STANOCH:
11 Q. Welcome back, Mr. Nassall.
12 Yes or no, did you speak with your
13 counsel during the break?
14 A. Yes, I did.
15 Q. You learned from ZHP about
16 the nitrosamine issues in valsartan API
17 in June 2018, right?
18 A. That's correct.
19 MR. STANOCH: I'm going to
20 mark an exhibit. Teva 320. Stand
21 by. I'll state for the record,
22 it's Bates ending 102401.
23 (Document marked for
24 identification as Exhibit

Page 159

1 Teva-320.)
2 BY MR. STANOCH:
3 Q. Let me know when you can
4 access that document, sir.
5 A. One moment. Yes, I have
6 access.
[REDACTED]

Page 160

[REDACTED]

Page 161

[REDACTED]

Page 162

[REDACTED]

Page 164

1 A. Yeah.

2 Q. And it was you and

3 Mr. Fluch, and anyone else you recall

4 from Teva?

5 A. I -- I would say it's only

6 the two of us.

7 Q. Who from ZHP attended?

8 A. Okay. I do recall that

9 there was Mr. Cai.

10 Q. T-S-A-I?

11 A. C-A-I.

12 Q. C -- oh, yes, C-A-I. Thank

13 you.

14 A. And Karen Xu, X-U.

15 Q. X-U. Thank you.

16 A. I'm not sure who else from

17 ZHP.

18 Q. And what do you recall were

19 Mr. Cai and Ms. Xu's roles at ZHP?

20 A. The official titles at that

21 time, for me, Mr. Cai was the highest

22 ranking sales and marketing guy at ZHP.

23 Ms. Xu was directly reporting to him, she

24 was also relatively high ranking, and

Page 163

[REDACTED]

19 Q. So I just want to go through

20 the timeline to make sure we have it

21 right.

22 So you were in China and you

23 were having dinner preplanned already

24 with ZHP representatives on June 20th?

Page 165

1 most of the time responsible for dealing

2 with Teva I would say.

3 I can't hear you.

4 Q. My apologies.

5 When was this June 20th

6 dinner with ZHP planned?

7 A. I do not fully recall. What

8 is usually happening is that CPhI thing

9 closes somewhere between 6 and 7, and

10 then you usually -- if you have a dinner

11 scheduled you go directly from the fair

12 to dinner, so I would say that dinner was

13 scheduled at 8.

14 Q. Thank you. And I guess I

15 was imprecise.

16 Was the dinner planned that

17 same day or had you had a schedule

18 predating the conference where the dinner

19 was scheduled to happen?

20 A. Okay. So that was

21 prescheduled.

22 Q. Had you -- so someone at

23 Teva had had contact with ZHP prior to

24 June 20th to schedule the dinner that you

Page 166

1 had?

2 A. And also to schedule the

3 meeting, like all the meetings during --

4 during that thing, we had all of that

5 prescheduled.

6 Q. Got it. And approximately

7 when did -- did you schedule the meetings

8 with ZHP you were going to have at the

9 conference as well as the dinner you had

10 with them?

11 A. I can't recall. Usually

12 this happens maybe two or three weeks in

13 advance.

14 Q. That's fair. And was that

15 you personally doing the schedule or did

16 Mr. Fluch handle it?

17 A. I can't recall how it was in

18 this special case for ZHP.

19 It could even be that

20 someone from our China office did this

21 for us, so...

22 Q. Understood.

23 Was there a particular

24 agenda or list of topics for your

Page 167

1 meetings or dinner with ZHP at the CPH

2 conference?

3 A. I can't recall in 2018.

4 Depending if there was a certain project

5 that required special attention, then it

6 was mentioned on the agenda.

7 But most of the time,

8 especially during the CPHI events, it's a

9 very -- you know, there's no specific

10 agenda. You run through whatever happens

11 until then.

12 Q. Did you discuss valsartan

13 with anyone at ZHP at the event prior to

14 the June 20, 2018 dinner?

15 A. As far as I recall, no.

16 Q. And did you meet with any

17 ZHP people prior to the June 20th dinner

18 at the conference?

19 A. Mm-hmm.

20 I can't recall if that was

21 before or after.

22 Q. Okay. So you are at the

23 conference. The conference that day

24 wraps up. You go to dinner with

Page 168

1 Mr. Fluch, with Mr. Cai, and Ms. Xu.

2 What do they convey to you

3 and Mr. Fluch about the valsartan API

4 issues?

5 A. So at the end of the dinner,

6 they said that they have they have

7 important topic which they still need to

8 discuss with us.

9 They mainly showed us the

10 e-mail they are about to send. So like

11 giving us a few minutes of a heads-up.

12 And asking us so what do you think about

13 it. There was -- there was no more

14 information than what was in the e-mail.

15 Let's put it that way.

16 Q. Right. That was going to be

17 my next question.

18 Was there anything else

19 specific discussed about the valsartan

20 API at the dinner that you recall?

21 A. No, I don't recall anything

22 else. It was mainly the message that

23 they have found a potentially genotoxic

24 impurity in the valsartan.

Page 169

1 Q. Did they give you any more

2 information about the nature of the

3 impurity?

4 A. No.

5 Q. Did they mention it was a

6 nitrosamine potentially?

7 A. At that point of time, what

8 they said is that they don't know what

9 structure, what compound it is.

10 Q. Did they tell you how they

11 found it?

12 A. I mean by testing for it.

13 But no, I don't -- no, I don't -- they

14 didn't say how they found it.

15 Q. I mean it's my understanding

16 that another customer of ZHP's brought

17 the issue to their attention. Is that

18 your understanding?

19 A. This is also what we heard

20 by -- I mean at that point of time,

21 especially after -- the day after, we

22 obviously also asked other potential

23 manufacturers of sartan APIs and

24 intermediate manufacturers what they

Page 170

1 heard. I mean, overnight it became the
2 industry talk.
3 And what I heard from
4 manufacturers of this API is that some,
5 some of the customers somehow were
6 involved.
7 Q. Okay. I just want to go
8 through the whole timeline.
9 So after the dinner on
10 June 20th, this e-mail goes out to you
11 and others. You forwarded it on, as you
12 testified earlier.
13 Next day, June 21st. Okay?
14 That's where I am now.
15 You remain in China that
16 day?
17 A. Yes.
18 Q. Okay. When did you come
19 back from China to your office in
20 Germany?
21 A. I think this was only more
22 than a week later. I can't remember the
23 exact date. But I am pretty sure that I
24 stayed at least one more week after CPhI

Page 171

1 ended. So it must have been the very end
2 of June, maybe even early July.
3 Q. Did you stay there on work
4 or did you take a holiday after the
5 convention?
6 A. No, that was on work.
7 Q. And you stayed in the Teva
8 Shanghai office?
9 A. Teva Shanghai office. And
10 we also had some more meetings after CPhI
11 with other manufacturers.
12 Q. Did you have any
13 conversations with anyone else at ZHP
14 about the valsartan API issues after
15 June 20th for that next week while you
16 are in China?
17 A. So after that, we learned
18 that from ZHP, there were several, you
19 know, not necessarily in the scheduled
20 meetings which we had with some
21 manufacturers, but with people you meet
22 during -- during CPhI and if we knew that
23 this company we're currently at, people
24 stopping by, that they also manufacture

Page 172

1 valsartan or intermediate for valsartan,
2 then we obviously tried asking what do
3 they know, have they heard, and to find
4 out some more information on what was
5 going on.
6 Q. Who do you -- strike that.
7 Which companies'
8 representatives do you recall talking to
9 to find out more information about the
10 valsartan API issues at ZHP?
11 A. For finding out what's going
12 on at ZHP, we only talked with ZHP
13 people.
14 Q. Okay.
15 A. But in general, the question
16 was there were other manufacturers for
17 valsartan. And whomever -- if I had a
18 meeting with such a company and I know
19 they also manufacture valsartan, then I
20 also asked them, have you heard, what
21 about yours, you know.
22 Q. Do you recall which
23 suppliers' representatives you had that
24 type of conversation with, if anyone?

Page 173

1 A. There for sure were several.
2 Especially also with all the intermediate
3 manufacturing which is happening in
4 China.
5 I do recall one that was to
6 Zhejiang Tianyu. Tianyu.
7 Q. If you can, I'm going to ask
8 you to spell that for the benefit of the
9 court reporter, sir.
10 A. Sure. So Zhejiang is the
11 province, that's Z-H-E-J-I-A-N-G --
12 Q. That's what I would --
13 that's what I would mispronounce as
14 Zhejiang, right?
15 A. Okay, yeah.
16 MR. STANOCH: The same
17 thing, madam court reporter.
18 BY MR. STANOCH:
19 Q. Go ahead, sir.
20 A. And the company name,
21 Tianyu, that's T-I-A-N-Y-U.
22 Q. Thank you.
23 What do you recall
24 discussing with, I'll call it Tianyu,

Page 174

1 about valsartan API at that time?

2 A. So I knew that they are one

3 of the biggest intermediate manufacturers

4 for not only valsartan, but for many

5 valsartan -- for many sartan, also other

6 sartans. And I knew that they are also

7 producing valsartan.

8 So I asked them if they have

9 heard from Huahai and what -- what they

10 think.

11 As you seen the statement

12 from Huahai, so far was only that they

13 have found an unknown impurity which is

14 potentially genotoxic.

15 So the question was, have

16 they heard, and the answer most of the

17 time was yes. Because as I said, it was

18 relatively quick news to everyone.

19 And then the question was

20 also if they have it in their product --

21 and not because I'm concerned about

22 Tianyu's product in this case, but to

23 find out if they maybe already know more

24 than this very basic statement that

Page 175

1 there's an unknown impurity.

2 Q. And forgive me. Did you say

3 if you had any person-to-person

4 communications with anyone else at ZHP

5 after the June 20th dinner about the

6 valsartan API issues?

7 A. If I recall it correctly,

8 then I had no further personal

9 interaction after that.

10 Q. Got it. So the day after

11 the dinner, you didn't go back to the ZHP

12 booth or talk to any ZHP representatives

13 while you were still in China, right?

14 A. I didn't. The schedule was

15 full with other meetings. And especially

16 on the very next day, it was just there

17 is an unknown impurity. I was also

18 trying to await for feedback from our

19 quality team, how serious they consider

20 this. And we were sure that we anyhow

21 would need to wait for the details, what

22 it exactly is, and if it's really

23 genotoxic.

24 Q. Right. And then you were in

Page 176

1 China for about a week after the dinner.

2 At any point in that week,

3 did you talk in person with any ZHP

4 representative or call any of them on the

5 phone about the valsartan API issues?

6 A. I am not totally sure. It

7 very well was possible that I might have

8 called them, either -- probably most

9 likely would have been Karen. But I

10 can't recall if that was in the week

11 while I was still in China or only after

12 I was back.

13 Q. Did you have a company

14 issued phone at the time?

15 A. Yes.

16 Q. Okay. Do you still have the

17 same phone today?

18 A. Yes.

19 Q. Same number --

20 A. Not -- the same number.

21 Q. Same number. I hope it's a

22 different phone, sir. Although mine is

23 pretty old as well.

24 A. That's what mine is now.

Page 177

1 Q. Earlier you had mentioned

2 you somehow learned or heard from someone

3 else that the contamination -- that the

4 issue with valsartan API at ZHP was told

5 to ZHP about -- from a customer, I think?

6 Isn't that -- you said something to that

7 effect?

8 A. There were many different

9 stories not only the next day, but also

10 in the following weeks.

11 I have to say that it never

12 came to a final conclusion, at least not

13 to me, of what was just a rumor. What

14 might have some, some parts of truth

15 there or not.

16 So one of the things we

17 heard is that it might have been because

18 of a potential customer who was

19 interested in buying the material from

20 ZHP, that they found it or had the

21 suspicion that it could be there. I

22 don't know exactly how it was.

23 Q. What rumors did you hear

24 about which customers might have told ZHP

Page 178

Page 180

¹ about the contamination in the valsartan
² API?

3 I'm focused just on the time
4 period while you are in China after the
5 June 20th dinner, sir.

6 A. Okay. Then I would say that
7 during that time, I didn't hear it yet.

⁸ Q. Eventually you did?

⁹ A. Again, it's rumors so...

10 Q. Understood, sir.

¹¹ Understood.

What do you recall hearing
about the customer or customers who
informed ZHP about the issue?

15 A. That was Novartis and
16 Sandoz. And I don't know if they really
17 informed them or if they asked them the
18 right questions so that they would look
19 for. And as I said, this is what -- what
20 I would say are rumors.

21 Q. I understand.

22 Did you ever talk to anyone
23 at Novartis or Sandoz about the ZHP
24 valsartan API contamination issues?

¹ Q. Thank you.

2 Do you recall whether, in
3 the month prior to the conference in
4 China, whether ZHP asked Teva to place
5 new orders for valsartan ASAP?

⁶ A. No, I don't recall that.

7 MR. STANOCH: I'm going to
8 put a document up real quick.
9 Stand by, sir. Teva 321.

(Document marked for
identification as Exhibit
Teva-321.)

13 MR. STANOCH: For the
14 record, it's 872512, Bates ending.

¹⁵ BY MR. STANOCH:

16 Q. Sir, just let me know when
17 you can access that document.

¹⁸ A. I have it open.

19 Q. Very good.

Page 179

Page 181

¹ A. No, I did not.

2 Q. Are you aware of anyone at
3 Teva who did so?

⁴ A. I would not think so.

⁶ Sandoz, Novartis, and Teva.

7 Q. Do you recall hearing
8 chitchat about when Novartis or Sandoz
9 informed ZHP about the valsartan API
10 contamination issues?

11 A. No.

Q. Other than Tianyu, do you recall any other specific companies' representatives whom you discussed the valsartan API contamination issues with while you were still in China after the June 20th dinner with ZHP?

18 A. No, I don't recall any
19 specific companies.

20 Q. Do you recall who you spoke
21 with at Tianyu?

22 A. Most likely, this should
23 have been -- I'm trying to recall his
24 name. Benny Wu? I'm not sure.

Page 182

[REDACTED]

Page 184

[REDACTED]

Page 183

[REDACTED]

Page 185

[REDACTED]

Page 186

Page 188

Page 187

Page 189

Page 190

10 Q. Yeah.

11 MR. STANOCH: Stand by for

12 the next exhibit, sir.

13 Sorry, let me repeat that,

14 sir.

15 BY MR. STANOCH:

16 Q. After receiving the

17 notifications from ZHP in June 2018 about

18 the valsartan API issues, did Teva

19 attempt to identify alternate sources of

20 valsartan API?

21 A. Again, sir, you wanted to

22 pull up an exhibit. There's nothing

23 right now, right?

24 Q. There's no exhibit now. You

Page 191

1 can put the exhibit away. Sorry.

2 A. We're still reloading the

3 page.

4 Q. No, I understand. I'm

5 sorry, sir. If we were in the same room,

6 I'd hand you a piece of paper.

7 A. Yeah, I know.

8 Q. Thank you for bearing with

9 me.

10 A. So, sorry, again, what was

11 the question now?

12 Q. After Teva received the

13 notifications from ZHP in June of 2018

14 about the valsartan API contamination

15 issues, did Teva attempt to identify

16 alternate sources for valsartan API?

17 A. So this -- this -- after

18 June '18 is a very long period of time.

19 And, yes, we were also looking into

20 potential alternate sources.

21 Q. I'm now marking Teva 332,

22 Bates ending 609197.

23 (Document marked for

24 identification as Exhibit

Page 192

1 Teva-322.)

2 MR. STANOCH: I'm so sorry.

3 Thank you, counsel.

4 Teva 322. I did it again.

5 THE WITNESS: No problem.

6 I've got it.

7 I have it open.

8 BY MR. STANOCH:

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

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19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 194

[REDACTED]

Page 196

1 A. Sure, yes.
2 Q. Do you recall the restaurant
3 you went to?
4 A. Three years ago. Not the
5 exact name. But you too -- there was a
6 common misunderstanding between, between
7 ZHP and us, and I always believed that
8 they want to go to steakhouses and they
9 always believe that I want to go to
10 steakhouses. So we usually ended up in a
11 steakhouse. I can't recall which one.
12 Q. Okay. And that was in
13 Shanghai where the convention was?
14 A. Yes.
15 Q. And do you recall just
16 generally about how long the whole dinner
17 was from start to finish, from when you
18 arrived to when you left?
19 A. So usually it's -- the
20 Chinese dinners are pretty -- pretty
21 quick. In Shanghai it can be a little
22 bit longer due to all the -- everyone
23 after the fair is doing this. So my
24 assumption would be that it probably was

Page 195

[REDACTED]

19 Q. You can put that aside for
20 now. Thank you, sir.
21 Just before I forget, I just
22 want to go back very briefly to the
23 dinner that you had on June 20th with
24 Mr. Cai and was it Ms. Xu?

Page 197

1 from 8 to 10 or 11.
2 Q. Fine. I will not get so
3 granular to ask you what you ate that
4 day, sir, so don't worry.
5 And who paid for the dinner,
6 you and Mr. Fluch or the ZHP personnel?
7 A. As this was in Shanghai, I'm
8 pretty sure that at the end it was ZHP.
9 MR. STANOCH: Stand by for
10 the next exhibit, sir.
11 (Document marked for
12 identification as Exhibit
13 Teva-323.)
14 MR. STANOCH: Teva 323.
15 Will be Bates ZHP01090696. Please
16 stand by, sir.
17 BY MR. STANOCH:
18 Q. Please let me know when you
19 can access that document.
20 A. I have it open now.
[REDACTED]

Page 198

[REDACTED]

Page 200

[REDACTED]

Page 199

[REDACTED]

Page 201

[REDACTED]

Page 202

[REDACTED]

Page 204

[REDACTED]

Page 203

[REDACTED]

Page 205

[REDACTED]

2 BY MR. STANOCH:
3 Q. You can put this aside for
4 now. Thank you.
5 A. Okay.
6 MR. STANOCH: Next exhibit,
7 Teva 324, Bates ending
8 ZHP02321449.
9 (Document marked for
10 identification as Exhibit
11 Teva-324.)
12 BY MR. STANOCH:
13 Q. Let me know when you can
14 access the document, sir.
15 A. 324, open now.

[REDACTED]

Page 206

[REDACTED]

Page 208

[REDACTED]

Page 207

[REDACTED]

Page 209

[REDACTED]

Page 210

[REDACTED]

Page 212

[REDACTED]

Page 211

[REDACTED]

6 Q. You can put that aside.
7 Thank you, sir.
8 MR. STANOCH: Teva 325.
9 (Document marked for
10 identification as Exhibit
11 Teva-325.)
12 MR. STANOCH: Bates ending
13 103279.
14 BY MR. STANOCH:
15 Q. Please let me know when you
16 can access that, sir.
17 A. 325, open.

[REDACTED]

Page 213

[REDACTED]

Page 214

[REDACTED]

Page 216

[REDACTED]

Page 215

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Page 217

[REDACTED]

Page 218

[REDACTED]

Page 220

[REDACTED]

8 Q. You can put that aside.

9 Thank you, sir.

10 MR. STANOCH: Stand by for

11 the next exhibit.

12 (Document marked for

13 identification as Exhibit

14 Teva-326.)

15 MR. STANOCH: Teva 326.

16 Bates ending 00036505.

17 BY MR. STANOCH:

18 Q. Please let me know when you

19 can access that exhibit, sir?

20 A. I opened it.

[REDACTED]

Page 219

[REDACTED]

Page 221

[REDACTED]

Page 222

[REDACTED]

Page 224

[REDACTED]

18 MR. STANOCH: I'll mark the
19 next exhibit, sir. Teva 327.
20 Bates ending 53929.
21 Document marked for
22 identification as Exhibit
23 Teva-327.)
24 BY MR. STANOCH:

Page 223

[REDACTED]

Page 225

1 Q. Please let me know when you
2 can access that document.
3 A. 227. Yes, have it.

[REDACTED]

Page 226

[REDACTED]

Page 228

[REDACTED]

Page 227

[REDACTED]

Page 229

[REDACTED]

24 MS. LOCKARD: No, no, no.

Page 230

1 That is not the rule. The judge
2 has ruled otherwise.
3 "Objection to form" is not
4 an appropriate objection. We
5 are --
6 MR. STANOCH: It's not?
7 "Objection to form" is not
8 appropriate?
9 MS. LOCKARD: You can
10 review -- you can review Judge
11 Vanaskie's ruling on this.
12 He said we are entitled to
13 give a basis for our form
14 objection, and that, in fact, we
15 should be giving a basis for our
16 form objection.
17 MR. STANOCH: Are you done
18 with your speaking objection,
19 counsel?
20 Are you done?
21 MS. LOCKARD: No, I was
22 responding to you.
23 BY MR. STANOCH:

Page 231

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Page 234

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Page 236

[REDACTED]

Page 235

[REDACTED]

Page 237

[REDACTED]

17 Q. Okay. Let's look at
18 Teva 328.
19 MR. STANOCH: Stand by.
20 (Document marked for
21 identification as Exhibit
22 Teva-328.)
23 BY MR. STANOCH:
24 Q. Tell me when you can access

Page 238

1 that. It's exhibit -- Bates ending
2 42244.
3 A. Yes. Have it open.

[REDACTED]

Page 240

[REDACTED]

Page 239

[REDACTED]

Page 241

[REDACTED]

Page 242

[REDACTED]

Page 244

[REDACTED]

Page 243

[REDACTED]

5 Q. I'm going to mark the next
6 exhibit, sir. Teva 329. Let me know
7 when you can access it.
8 (Document marked for
9 identification as Exhibit
10 Teva-329.)
11 MR. STANOCH: For the
12 record, it's Bates ending 109885.
13 THE WITNESS: I have it
14 open.
15 BY MR. STANOCH:
[REDACTED]

Page 245

[REDACTED]

20 BY MR. STANOCH:
21 Q. Did Teva ever ask Mylan to
22 test valsartan API it was selling to Teva
23 for nitrosamines?
24 A. Again, this is a question

Page 246

1 for quality. I'm not prepared and did
2 not check on what we tested and when we
3 tested.
4 Q. Well, you're designated on
5 the communications with API suppliers,
6 including ZHP and Mylan, right?
7 A. Yeah, you are right.
8 Q. And you and Mr. Fluch, in
9 fact, were some of the point people
10 communicating with Mylan at this time
11 concerning nitrosamine issues, correct?
12 A. That is also correct.
13 Q. Did you or Mr. Fluch or
14 anyone else at Teva ask Mylan, we'll say
15 in August 2018, to test valsartan APIs
16 for nitrosamines?
17 A. And that would have been my
18 next sentence.
19 I'm not -- I'm not
20 100 percent sure of the exact timing.
21 But I'm pretty sure that we at some point
22 of time also asked Mylan for testing of
23 several of the nitrosamines.
24 Q. And the Mylan -- we can look

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1 at the e-mail, sir, for sure, I'm sure
2 you are aware of them. Mylan never got
3 back to Teva until November 2018; is that
4 right?
5 A. Again, I don't recall the
6 exact dates. And if you have something,
7 please feel free to show me, to help me
8 recall. So I don't know the exact
9 timelines when.
10 Q. Okay. We can go through the
11 e-mails.
12 But sitting here right now,
13 do you recall one way or the other of
14 whether Mylan provided nitrosamine
15 testing results to Teva for valsartan API
16 in August 2018?
17 A. Without looking at the
18 e-mails, I don't recall for sure at which
19 point of time they did. Because this was
20 one -- you know, really one long process
21 from June for the next six months, until
22 everything was clearer.
23 Q. Same question. Sitting here
24 right now, one way or the other, can you

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1 say whether Mylan provided nitrosamine
2 testing results to Teva in September or
3 October of 2018?
4 A. And again, I don't recall by
5 heart when we got the testing results.
6 Q. Mm-hmm. Do you think it was
7 before or after Teva instituted its
8 recall of finished dose valsartan that
9 contained Mylan valsartan API?
10 A. And again, by heart, I don't
11 recall the order of each of the events.
12 Q. Do you think it would be
13 important to have the test results sooner
14 rather than later from Mylan?
15 MS. LOCKARD: Objection.
16 Vague. Outside the scope of the
17 deposition.
18 THE WITNESS: And again, as
19 mentioned before, there were so
20 many topics happening all at the
21 same time. And we asked for
22 testing of hundreds of batches.
23 And it was not only Teva asking
24 for that. There are many other

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1 customers for -- for all the
2 manufacturers we are talking here
3 about, and they also asked.
4 And I'm pretty sure that
5 both ZHP and Mylan did whatever
6 was within the capabilities of
7 their testing.
8 BY MR. STANOCH:
9 Q. After this revelation in
10 August 2018 that older process valsartan
11 API from ZHP is contaminated with NDMA as
12 well, can you still believe you could
13 trust ZHP?
14 MS. LOCKARD: Objection to
15 the form. Mischaracterizes the
16 evidence. Vague.
17 THE WITNESS: I mean, this
18 again is the same as before. It's
19 a developing story. And I fully
20 trust that our manufacturers told
21 us what they knew at the time when
22 they told us.
23 And then the situation
24 changes and you find out some new

Page 254

[REDACTED]

Page 256

[REDACTED]

17 Q. Well, let's take a look at
18 Exhibit 331.
19 (Document marked for
20 identification as Exhibit
21 Teva-331.)
22 MR. STANOCH: For the Bates,
23 it's ZHP009129692.
24 BY MR. STANOCH:

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[REDACTED]

Page 257

1 Q. Let me know when you can
2 access that document, sir.
3 A. Yes, I have it.

[REDACTED]

Page 258

[REDACTED]

Page 260

[REDACTED]

Page 259

[REDACTED]

Page 261

[REDACTED]

Page 262

[REDACTED]

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Page 278

[REDACTED]

Page 280

[REDACTED]

Page 279

[REDACTED]

Page 281

[REDACTED]

Page 282

[REDACTED]

20 Q. All right.
21 MR. STANOCH: Teva 332.
22 (Document marked for
23 identification as Exhibit
24 Teva-332.)

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1 BY MR. STANOCH:
2 Q. Please tell me when you can
3 access it.
4 MR. STANOCH: It's Bates
5 ending 137077.
6 THE WITNESS: Yes, I have it
7 open.
8 BY MR. STANOCH:
[REDACTED]

Page 284

[REDACTED]

Page 285

[REDACTED]

Page 286

[REDACTED]

Page 288

1 BY MR. STANOCH:
2 Q. Tell me when you can access
3 it.
4 A. One second. I have it.

[REDACTED]

Page 287

[REDACTED]

21 MR. STANOCH: Teva 333.
22 (Document marked for
23 identification as Exhibit
24 Teva-333.)

Page 289

[REDACTED]

Page 290

[REDACTED]

Page 292

[REDACTED]

Page 291

[REDACTED]

Page 293

[REDACTED]

Page 294

[REDACTED]

Page 296

[REDACTED]

Page 295

[REDACTED]

Page 297

[REDACTED]

MR. STANOCH: Next exhibit, sir.

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1 Teva -- it should be 334.
2 Give me one -- let me try that
3 again.
4 THE WITNESS: Yes.
5 (Document marked for
6 identification as Exhibit
7 Teva-334.)
8 BY MR. STANOCH:
9 Q. Teva 334, sir.
10 A. All right. It's loading.
11 Go ahead.
12 MR. STANOCH: It's Bates
13 ending 423475.
14 BY MR. STANOCH:

[REDACTED]

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[REDACTED]

Page 300

[REDACTED]

Page 301

[REDACTED]

Page 302

[REDACTED]

Page 304

[REDACTED]

Page 303

[REDACTED]

Page 305

[REDACTED]

Page 306

7 MR. STANOCH: Next exhibit,
8 sir. 335.
9 (Document marked for
10 identification as Exhibit
11 Teva-335.)
12 BY MR. STANOCH:
13 Q. Tell me when you can --
14 stand by.
15 MR. STANOCH: For the
16 record --
17 THE WITNESS: I have it up.
18 MR. STANOCH: Very good.
19 I'll state for the record, it's
20 Bates ending 55166.
21 BY MR. STANOCH:

[REDACTED]

Page 307

[REDACTED]

Page 308

[REDACTED]

Page 309

[REDACTED]

Page 310

[REDACTED]

Page 312

[REDACTED]

4 BY MR. STANOCH:

5 Q. Mm-hmm. Mm-hmm. I'm going

6 to move up in time to make sure we cover

7 and talk about some indemnification

8 issues now. Okay?

9 A. Okay.

10 Q. And which entities, if any,

11 has Teva requested indemnification of in

12 connection with valsartan API and

13 nitrosamines?

14 A. So there is a settlement

15 agreement with ZHP which covers some

16 areas. With all other valsartan

17 manufacturers, there is no written

18 agreement. With Mylan, there was only --

19 we -- got the -- the API which we could

20 not use anymore was refunded to us.

21 Q. Okay. I'll start with ZHP.

22 So first, ZHP valsartan API that Teva had

23 on hand at the moment Teva initiated

24 recalls, is it correct that ZHP offered

Page 311

[REDACTED]

Page 313

1 to refund Teva for that unused valsartan

2 API?

3 A. If I recall correctly, then

4 yes, this is what they offered and

5 probably it would make any further

6 questions easier if we can have a look at

7 the settlement agreement.

8 MR. STANOCH: Sure. Teva

9 336.

10 (Document marked for

11 identification as Exhibit

12 Teva-336.)

13 BY MR. STANOCH:

14 Q. Tell me when you can access.

15 A. Yep. Got it.

[REDACTED]

<div>Page 314</div> <div>[REDACTED]</div>	<div>Page 316</div> <div>[REDACTED]</div>
<div>Page 315</div> <div>[REDACTED]</div>	<div>Page 317</div> <div>[REDACTED]</div>

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Page 324

[REDACTED]

Page 323

[REDACTED]

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[REDACTED]

Page 326

[REDACTED]

Page 328

[REDACTED]

12 MR. STANOCH: And I'll mark
13 Teva 337.
14 (Document marked for
15 identification as Exhibit
16 Teva-337.)
17 BY MR. STANOCH:
18 Q. Tell me when you can see it.
19 A. Correct.

[REDACTED]

Page 327

[REDACTED]

Page 329

[REDACTED]

7 MR. STANOCH: Why don't we
8 take a break.
9 THE VIDEOGRAPHER: The time
10 right now is 6:42 p.m. We are off
11 the record.
12 (Short break.)
13 THE VIDEOGRAPHER: The time
14 right now is 7:06 p.m. We're back
15 on the record.
16 BY MR. STANOCH:
17 Q. Welcome back, Mr. Nassall.
18 Again, yes or no, did you talk to your
19 counsel during our break?
20 A. Yes, I did.
21 Q. Did Teva continue to source
22 valsartan API from Mylan after the
23 nitrosamine issues?
24 A. Not for the U.S. But in

Page 330

1 general, yes.
2 Q. Right, right. Because Teva
3 discontinued selling valsartan products
4 in the U.S., right?
5 A. Yes. That's correct.
6 Q. Right. And then so to this
7 day, Teva is sourcing valsartan API for
8 non-U.S. markets from Mylan?
9 A. Yes, we do, yes.
10 MR. STANOCH: I think that's
11 all the questions I have for now.
12 I appreciate your time, especially
13 with the time zone, and I
14 appreciate that English is not
15 your native language, so I
16 appreciate it.
17 And I'll reserve any time I
18 have left until after Ms. Lockard
19 questions you.
20 THE WITNESS: Welcome.
21 - - -
22 EXAMINATION
23 - - -
24 BY MS. LOCKARD:

Page 332

[REDACTED]

Page 331

1 Q. Mr. Nassall, thank you for
2 your patience. It's Victoria Lockard for
3 Teva. Just a few follow-up questions for
4 you.
[REDACTED]

Page 333

[REDACTED]

Page 334

[REDACTED]

Page 336

[REDACTED]

Page 335

[REDACTED]

Page 337

[REDACTED]

Page 338

[REDACTED]

Page 340

[REDACTED]

Page 339

[REDACTED]

Page 341

[REDACTED]

Page 342

[REDACTED]

Page 344

[REDACTED]

19 Q. Just one moment. Bear with
20 me.
21 A. Okay.
22 MS. LOCKARD: Okay. I think
23 those are all the questions I have
24 for you, Mr. Nassall. Thank you

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[REDACTED]

Page 345

1 for your patience today.
2 We'll see if Mr. Stanoch has
3 anything else.
4 MR. STANOCH: I have no
5 further questions.
6 MS. LOCKARD: Okay.
7 MR. STANOCH: Off the
8 record.
9 THE VIDEOGRAPHER: The time
10 right now is 7:25 p.m. We're off
11 the record.
12 MS. LOCKARD: We'll reserve
13 the right to read and sign the
14 deposition.
15 MR. STANOCH: Okay.
16 (Excused.)
17 (Deposition concluded at
18 approximately 7:25 p.m. Central
19 European Summer Time.)
20
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CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, JENS NASSALL, have the opportunity to read and sign the deposition transcript.

MICHELLE L. GRAY,
 A Registered Professional
 Reporter, Certified Shorthand
 Reporter, Certified Realtime
 Reporter and Notary Public
 Dated: July 2, 2021

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 350, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

 JENS NASSALL DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

 Notary Public

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Exhibit 91

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY

2

3 IN RE: VALSARTAN, : MDL NO. 2875
 LOSARTAN, AND :
 4 IRBESARTAN PRODUCTS : HON. ROBERT
 LIABILITY LITIGATION : B. KUGLER

5

6 THIS DOCUMENT APPLIES :
TO ALL CASES :

7

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER
VOLUME I

10

11 March 9, 2021

12

13

Videotaped remote deposition of RICHARD DEREK GLOVER, taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:02 a.m., EST, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

19

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20

21 GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
22 deps@golkow.com

23

24

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I N D E X

Testimony of:
 RICHARD DEREK GLOVER
 By Mr. Davis 15

- - -

E X H I B I T S

- - -

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PL-Glover-3	Curriculum Vitae Richard Derek Glover Viatrix	28
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PL-Glover-5	Quality Risk Management SOP MYLAN-MDL287500369663	47

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PL-Glover-12	Quality Risk Assessment Usage of Recovered Solvents in Manufacturing MYLAN-MDL287500297981	120-93
PL-Glover-13	E-mail Thread 10/4/12 Subject, Valsartan Recovery Solvents/Materials MYLAN-MDL287500283572	120-75
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D E P O S I T I O N S U P P O R T I N D E X		
	PAGE	LINE
Direction to Witness Not to Answer		
Request for Production of Documents		
Stipulations		
Questions Marked		

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1 - - -
2 THE VIDEOGRAPHER: We are
3 now on the record. My name is
4 Ingrid Rodriguez. I'm a
5 videographer for Golkow Litigation
6 Services.
7 Today's date is March 9,
8 2021. And the time is 9:02 a.m.
9 This remote video deposition
10 is being held in the matter of In
11 Re Valsartan Losartan, and
12 Irbesartan Products Liability
13 Litigation, for the United States
14 District Court for the District of
15 New Jersey.
16 The deponent is Derek
17 Glover.
18 All parties to this
19 deposition are appearing remotely
20 and have agreed to the witness
21 being sworn in remotely.
22 Due to the nature of remote
23 reporting, please pause briefly
24 before speaking to ensure all

Page 15

1 parties are heard completely.
2 All counsel present will be
3 noted on the stenographic record.
4 The court reporter is
5 Michelle Gray and will now swear
6 in the witness.
7 - - -
8 ... RICHARD DEREK GLOVER,
9 having been first duly sworn, was
10 examined and testified as follows:
11 - - -
12 EXAMINATION
13 - - -
14 BY MR. DAVIS:
15 Q. Okay. Good morning,
16 Mr. Glover. How are you?
17 A. I'm good. Thank you.
18 Q. I'm just going to tell you
19 that I have like three monitors set up.
20 So if I'm not, you know, looking at you
21 directly on the screen, that doesn't mean
22 that I'm not paying attention. I
23 apologize for that.
24 Have you given a deposition

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1 before?
2 A. Yes, I have.
3 Q. Have you given a Zoom
4 deposition before?
5 A. I have not.
6 Q. Okay. Well, that makes two
7 of us. I've defended one. This is the
8 first one I'm taking. So hopefully we
9 can get through this with minimal
10 difficulties.
11 Let me just ask, do you have
12 a computer in front of you or what's the
13 camera there?
14 A. Yeah. We have a laptop
15 camera set up, and then I have a slightly
16 larger screen behind that I'm hoping will
17 help me read things.
18 Q. I'm just going to ask right
19 now that you disable any, if any are
20 open, any chat features or text features
21 on the laptop.
22 A. I don't see anything. It's
23 not mine, so I'm assuming that they've
24 already taken care of that.

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1 Q. Okay, great. You said you
2 had given some previous depositions
3 before.
4 How many total?
5 A. Just a couple.
6 Q. Okay. What were the nature
7 of the cases that you were deposed in?
8 A. One was a case years ago
9 where we disputed over the release or
10 rejection of a product. And the other
11 one was a longer time ago related to an
12 investigation at the site that I was
13 working in.
14 Q. What was the site?
15 A. Morgantown. Morgantown
16 facility.
17 Q. Okay. Approximately what
18 year was that?
19 A. I'm not exactly sure. 2009
20 maybe. 2010.
21 Q. Do you recall what the
22 nature of the investigation was?
23 A. Again, I apologize if it was
24 a deposition or maybe it was just some

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1 interviews related to a potential
2 deposition. It was prep work anyway. It
3 was related to an investigation
4 associated with the plant and some news
5 articles that were around about the
6 investigation.
7 Yeah. I don't know how else
8 to describe it. It was just an
9 investigation related to the
10 manufacturing facility.
11 Q. Who was conducting the
12 investigation?
13 A. I was, as head of quality at
14 the time.
15 Q. Was there an external
16 investigation or was this a purely
17 internal matter?
18 A. Internal matter. And
19 eventually it became a news article, and
20 so we ended up working with the FDA.
21 They came in and found no issues, which
22 basically stopped the entire inquiry.
23 Q. Okay. What were -- what was
24 the substance of the matter that was

Page 19

1 being investigated?
2 A. An investigation process for
3 in-process manufacturing controls.
4 Q. What was alleged to have
5 been done wrong?
6 A. There was no allegation. It
7 was simply a report that operators were
8 using the equipment improperly. And
9 again, we investigated it, found that
10 there was no evidence of them, you know,
11 doing anything inappropriate.
12 FDA inspected the facility
13 twice and found no issues as well.
14 Q. Okay. I'm going to attempt
15 to introduce my first exhibit here.
16 Let's see how this goes.
17 MR. DAVIS: Clem, for
18 naming, these exhibits, should I
19 just say Mylan for the prefix and
20 01? Or how would you prefer to do
21 that?
22 MR. TRISCHLER: Whatever you
23 prefer. If you want to mark them
24 Mylan -- why don't you mark them

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1 Plaintiffs' Exhibit 1. Plaintiff
2 Mylan-1, because it's your
3 exhibit, right?
4 MR. DAVIS: Yeah.
5 MR. HONIK: This is Ruben.
6 May I suggest you name them
7 Glover-1 and so forth. There are
8 going to be lots of Mylan
9 depositions.
10 MR. TRISCHLER: That's fine.
11 MR. DAVIS: Sure. Although
12 I thought we were trying to -- and
13 I don't know how other defendants
14 are doing it, but I think we were
15 supposed to do it sequentially,
16 you know, and reuse exhibits
17 throughout. And I'm not sure if
18 that's what CMO 20 says. But I'm
19 happy to do it whichever way.
20 MR. HONIK: We can re-number
21 them later. Why don't you call
22 them Glover-1 and so forth. We
23 can re-number if need be.
24 MR. DAVIS: Clem, are you

Page 21

1 okay with that?
2 MR. TRISCHLER: Sure.
3 MR. DAVIS: Okay. I'll call
4 it PL for plaintiff and then
5 Glover, and then one.
6 (Document marked for
7 identification as Exhibit
8 PL-Glover-1.)
9 MR. DAVIS: Okay. That
10 would be Tab 2 in the binder,
11 Clem, or at least that number
12 what -- so what I've done with the
13 file names was number them from
14 tab. So I'm not going to be going
15 sequentially through -- I'll
16 mostly be going sequentially
17 through, but in some cases I'm
18 going to be jumping around. But
19 the file name should start with a
20 two. It's the 30(b)(6) notice.
21 MR. TRISCHLER: Okay.
22 MR. DAVIS: Or actually,
23 rather -- sorry, the 30(b)(6)
24 topics, rather.

<p>Page 22</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. Mr. Glover, you can let me</p> <p>3 know when you've had a chance to put that</p> <p>4 in front of you?</p> <p>5 A. I have Exhibit A in front of</p> <p>6 me.</p> <p>7 Q. Okay. So that -- we're</p> <p>8 going to call that Plaintiff Glover-1,</p> <p>9 Exhibit 1 for this deposition.</p> <p>10 This is the Court's order</p> <p>11 with the 30(b)(6) topics in this case.</p> <p>12 And if you go to page -- rather, Exhibit</p> <p>13 C, which is Page 21 of 82 at the top. If</p> <p>14 you see the blue lettering at the top.</p> <p>15 You'll see Page 21 of 82. That starts</p> <p>16 with Exhibit C which is the 30(b)(6)</p> <p>17 topics for Mylan.</p> <p>18 A. Okay.</p> <p>19 Q. Have you reviewed this</p> <p>20 document before today?</p> <p>21 A. It doesn't look familiar to</p> <p>22 me.</p> <p>23 Q. So you don't think you</p> <p>24 reviewed it before today?</p>	<p>Page 23</p> <p>1 A. No.</p> <p>2 Q. Do you recognize that you're</p> <p>3 designated on approximately 24 or 25 of</p> <p>4 the topics that are listed on the next</p> <p>5 following pages?</p> <p>6 A. Yes, I read a notice</p> <p>7 previously. But it didn't look like this</p> <p>8 one.</p> <p>9 Q. Okay. That might be what I</p> <p>10 show you next. Let's, in fact, go to</p> <p>11 that now.</p> <p>12 MR. DAVIS: That would be</p> <p>13 Tab 3, Clem, which is the amended</p> <p>14 notice of deposition.</p> <p>15 (Document marked for</p> <p>16 identification as Exhibit</p> <p>17 PL-Glover-2.)</p> <p>18 MR. TRISCHLER: Yes, he has</p> <p>19 it.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Okay. Have you seen this</p> <p>22 document, Mr. Glover?</p> <p>23 A. Yes, sir.</p> <p>24 MR. TRISCHLER: And just to</p>	<p>Page 24</p> <p>1 be clear, John, what you said Tab</p> <p>2 3 is Exhibit 2, correct?</p> <p>3 MR. DAVIS: Exhibit 2.</p> <p>4 Right.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. So you have seen Exhibit 2,</p> <p>7 Mr. Glover?</p> <p>8 A. I have.</p> <p>9 Q. When did you first learn</p> <p>10 that you would be designated as a</p> <p>11 corporate representative to testify in</p> <p>12 this case?</p> <p>13 A. Approximately two -- two to</p> <p>14 three months ago.</p> <p>15 Q. At that point, did you</p> <p>16 have -- or did you also learn the topics</p> <p>17 on which you would be designated at that</p> <p>18 point?</p> <p>19 A. I got a general overview,</p> <p>20 yes.</p> <p>21 Q. Okay. Do you understand</p> <p>22 that you're here today to testify on</p> <p>23 behalf of Mylan Laboratories Limited,</p> <p>24 Mylan MB and Mylan Pharmaceuticals, Inc.?</p>	<p>Page 25</p> <p>1 A. Yeah.</p> <p>2 Q. Okay. So when I refer to</p> <p>3 Mylan in this case, can we agree that I'm</p> <p>4 referring to all of those entities</p> <p>5 inclusively?</p> <p>6 A. Okay.</p> <p>7 Q. Okay. And if there's -- at</p> <p>8 any point that you want to refer to one</p> <p>9 in particular, just let me know that.</p> <p>10 I'm just going to assume that when you</p> <p>11 say Mylan that you're referring to any</p> <p>12 and all unless you specifically tell me</p> <p>13 otherwise, and I'll do the same for you.</p> <p>14 If you go to the bottom of</p> <p>15 Exhibit 2, you'll see an exhibit --</p> <p>16 Exhibit B, which is on the second-to-last</p> <p>17 page.</p> <p>18 A. All right. So is this</p> <p>19 Exhibit 2 now? Or is that Exhibit 2?</p> <p>20 MR. TRISCHLER: You're</p> <p>21 holding Exhibit 2.</p> <p>22 THE WITNESS: Okay.</p> <p>23 The bottom of which page?</p> <p>24</p>
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1 BY MR. DAVIS:
2 Q. The bottom of the
3 second-to-last page, which is Page 8.
4 A. Okay.
5 Q. So there's two document
6 requests there, one being a CV which I
7 can represent that we've received.
8 The second is a production
9 of custodial documents. And I'll just
10 give you some background here. We don't
11 have a custodial file production for you
12 because one wasn't given to us.
13 Let me just ask, if it
14 becomes necessary for us to ask for a
15 custodial file in the future, did you
16 receive a litigation hold notice related
17 to this matter at any point?
18 MR. TRISCHLER: Just note my
19 objection, John, because you've
20 mischaracterized the record. A
21 request for custodial file was
22 made in the court on a motion by
23 plaintiff, and the court ordered
24 that no custodial production

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1 needed to be made for Mr. Glover.
2 So I think you've mischaracterized
3 the record.
4 MR. DAVIS: Well, sure. And
5 I'm not trying to dispute about
6 that.
7 I'm just saying in the
8 future if we need to again request
9 one as a result of this
10 deposition, for instance, I want
11 to see if his custodial file has
12 been preserved through, for
13 example, getting a litigation hold
14 letter.
15 So that's the extent of my
16 question.
17 BY MR. DAVIS:
18 Q. Did you receive a litigation
19 hold letter related to this litigation?
20 A. I don't have a specific
21 recollection of it. But it's standard
22 practice, so it's likely that I did.
23 Q. When you say standard
24 practice, does that go to everyone at the

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1 company?
2 A. Well, anyone at my level. I
3 don't know how far they go. But I
4 usually get them.
5 Q. What is your current title?
6 A. I'm the head of global
7 quality.
8 MR. DAVIS: I'm going to
9 introduce your CV as Exhibit 3.
10 (Document marked for
11 identification as Exhibit
12 PL-Glover-3.)
13 BY MR. DAVIS:
14 Q. Do you recognize this as
15 your CV?
16 A. Yes.
17 Q. And so you're head of global
18 quality. Who do you report to?
19 A. I report to Rajiv Malik.
20 Q. You report directly to
21 Mr. Malik?
22 A. Yes.
23 Q. And he's the president of
24 Mylan?

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1 A. Now Viatrix, yes.
2 Q. Now, Viatrix. Okay. I'm
3 just going to -- for my own sake, I've
4 been calling y'all Mylan for now --
5 A. Okay.
6 Q. -- so I'm going to keep
7 doing that if you don't mind.
8 A. That's fine.
9 Q. So when you say you're head
10 of global quality, does that include
11 quality assurance and quality control?
12 A. Sure. So quality control
13 and quality assurance being general
14 terms, and would be specific. Within our
15 global infrastructure we don't
16 necessarily have differentiated quality
17 control and quality assurance at the
18 global level or regional levels. Those
19 are typically, in our world, site-level
20 functions. But they do report up to me
21 through several layers.
22 Q. Is there -- at what point is
23 there a distinction between quality
24 assurance and quality control at Mylan?

<p>Page 30</p> <p>1 A. At the site level. 2 Q. At the site level. 3 What's -- just in general 4 terms, how would you describe the 5 difference between the two? What does 6 quality assurance do and what does 7 quality control do? 8 A. Within our company, the 9 terminology quality control is used 10 predominately as laboratory operations or 11 quality control laboratory operations. 12 It's typically the analytical testing 13 function within the quality program. 14 Quality assurance being a 15 host of other supporting 16 compliance-related functions and programs 17 within quality. 18 Q. So is one sort of more -- is 19 quality control sort of more 20 retrospective, meaning laboratory 21 analysis of stuff that's already been 22 done or materials that have already been 23 manufactured, whereas quality assurance 24 is more proactive on the front end</p> <p>Page 31</p> <p>1 ensuring quality? 2 MR. TRISCHLER: Objection to 3 form. 4 BY MR. DAVIS: 5 Q. Do I not have that right? 6 THE WITNESS: Do I answer 7 the question or -- 8 MR. TRISCHLER: You can 9 answer. Unless counsel wants to 10 rephrase or re-ask the question, 11 you should answer as best you can. 12 THE WITNESS: I mean, based 13 on the way you asked the question, 14 the answer would be no. 15 Quality control involves 16 testing and testing can be, you 17 know, realtime testing, stability 18 testing, a variety and host of 19 testing. 20 Quality assurance, also 21 influences both realtime, 22 historic, and proactive measures 23 that may be taking place. 24 There's nothing time bound</p>	<p>Page 32</p> <p>1 about quality control versus 2 quality assurance, I guess, is the 3 way I would probably try to answer 4 your question. 5 BY MR. DAVIS: 6 Q. Okay. That makes sense. So 7 it's -- I guess the distinction is more 8 just that quality control is more 9 laboratory-based whereas quality 10 assurance is everything else? 11 A. To the greater extent, yes. 12 Not exclusively, but definitely that's 13 where the focus is. 14 Q. As head of global quality, 15 does that give you oversight of all of 16 Mylan's manufacturing sites, whether 17 they're in India or the U.S. or anywhere 18 else? 19 A. Yes. 20 Q. When it comes to sort of 21 standardization of quality practices, is 22 each site sort of left to their own 23 devices or is there a concerted effort at 24 Mylan to have consistent quality related</p> <p>Page 33</p> <p>1 SOPs and practices at all the sites? 2 A. Each site has to have, and 3 maintains its own infrastructure and 4 program policies, you know, in accordance 5 with the regulatory laws. 6 You know, we do try to 7 establish, you know, some level of 8 standardization on particular topics 9 which is consistent within the industry, 10 but there's no way to standardize every 11 single topic or every single detail from 12 facility to facility or region to region. 13 That would be impossible. 14 Q. Which part -- you had 15 mentioned particular topics. Can you 16 give me some examples of those? 17 A. Yeah, key programs like 18 complaint investigations or 19 investigations in the plant, validation, 20 things like that. 21 Q. Okay. Validation, like 22 process validation? 23 A. Yes. 24 Q. What about risk management?</p>
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Page 34	Page 36
Page 35	Page 37
<p>1 A. I don't think there's a</p> <p>2 standardized policy on risk management at</p> <p>3 this point.</p> <p>4 Q. Can you describe what risk</p> <p>5 management is in the context of Mylan's</p> <p>6 quality efforts?</p> <p>7 A. Again, that's a hard</p> <p>8 question to answer.</p> <p>9 Risk management exists in</p> <p>10 dozens of different applications and</p> <p>11 interpretations. So you'd have to be</p> <p>12 more specific, I think.</p> <p>13 Q. Okay.</p> <p>14 MR. DAVIS: I'm marking</p> <p>15 Exhibit 4.</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 PL-Glover-4.)</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. Let me know when you have</p> <p>21 that in front of you and you've had a</p> <p>22 chance to view it.</p> <p>23 MR. TRISCHLER: By virtue of</p> <p>24 your last question, I'm assuming,</p>	<p>1 we have the correct -- we're</p> <p>2 talking about the same document.</p> <p>3 That's all.</p> <p>4 MR. DAVIS: Sure.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Mr. Glover, let me know when</p> <p>7 you've had a chance to review</p> <p>8 sufficiently to talk about it.</p> <p>9 A. Okay.</p> <p>10 Q. Do you recognize this as an</p> <p>11 FDA guidance document?</p> <p>12 A. I do.</p> <p>13 Q. Have you -- do you work with</p> <p>14 these documents in your role as head of</p> <p>15 quality at Mylan?</p> <p>16 A. I have somebody that is</p> <p>17 primarily responsible for this, but yes.</p> <p>18 Q. Okay. What does ICH stand</p> <p>19 for?</p> <p>20 A. I will screw up the acronym.</p> <p>21 It's like international committee for</p> <p>22 harmonization, something like that. It's</p> <p>23 a group that works on standardizing best</p> <p>24 practices within our industry.</p>
<p>1 pulled from the pile, Tab 5, which</p> <p>2 is Guidance For Industry, Q9</p> <p>3 Quality Risk Management. Is that</p> <p>4 your Exhibit 4, John?</p> <p>5 MR. DAVIS: Yes, that's</p> <p>6 right.</p> <p>7 MR. TRISCHLER: Okay. The</p> <p>8 issue that I have on this end,</p> <p>9 just so that, you know, my</p> <p>10 comments don't seem strange, is</p> <p>11 that when these were brought up</p> <p>12 from my copy center, Post Its of</p> <p>13 the tabs were put on everything.</p> <p>14 So what you just labeled as</p> <p>15 Exhibit 4, as opposed to 5 on it,</p> <p>16 so that's why I'm just trying to</p> <p>17 clarify.</p> <p>18 MR. DAVIS: Sure. And we're</p> <p>19 going to be moving away -- you</p> <p>20 know, the tabs are purely internal</p> <p>21 identifiers for me.</p> <p>22 MR. TRISCHLER: Right. No,</p> <p>23 I understand. I just want to make</p> <p>24 sure -- I just want to make sure</p>	<p>1 Q. Okay. And so these -- these</p> <p>2 FDA guidance documents that, you know,</p> <p>3 are referred to as like ICH 9 or</p> <p>4 something, for example, quality risk</p> <p>5 management, these are sort of setting for</p> <p>6 the best practices, as you say?</p> <p>7 A. Yeah. I think the</p> <p>8 intention -- FDA puts a disclaimer in all</p> <p>9 of their guidances that state that these</p> <p>10 are not legally enforceable but represent</p> <p>11 FDA's current thinking on a particular</p> <p>12 topic. Does not operate or bind FDA or</p> <p>13 the public. There's a big disclaimer on</p> <p>14 the front end that basically indicates</p> <p>15 that these are suggested practices.</p> <p>16 Q. Let me have you turn to Page</p> <p>17 6 of this document.</p> <p>18 A. I'm sorry, Page 6?</p> <p>19 Q. The numbering at the bottom.</p> <p>20 A. Okay.</p> <p>21 Q. One second. Actually,</p> <p>22 sorry, go back to start at Page 1, which</p> <p>23 is this -- I guess page -- numbered Page</p> <p>24 5. But it's numbered 1 at the bottom.</p>

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1 A. Okay.

2 Q. The FDA sort of has this

3 introduction section here, and they say

4 in the last sentence of the first

5 paragraph that the importance of quality

6 systems has been recognized in the

7 pharmaceutical industry and it is

8 becoming evident that quality and risk

9 management is a valuable component of an

10 effective quality system.

11 Does Mylan agree with that?

12 A. As a general statement, the

13 value of quality risk management, yes, we

14 agree.

15 Q. If you flip to the next

16 page, the first paragraph right in the

17 middle there, it says, "An effective

18 quality risk management approach can

19 further ensure the high quality of the

20 drug product to the patient by providing

21 a proactive means to identify and control

22 potential quality issues during

23 development and manufacturing."

24 Does that strike you as a

Page 39

1 pretty good definition of quality risk

2 management?

3 A. I interpret that as an

4 example of what a quality risk management

5 program may achieve.

6 Q. So a proactive means to

7 identify and control potential quality

8 issues during development and

9 manufacturing. Do you disagree with that

10 as a good definition of quality risk

11 management?

12 MR. TRISCHLER: Objection to

13 form. Asked and answered.

14 You can answer.

15 THE WITNESS: Yeah, I -- can

16 you ask the question again? I'm

17 sorry.

18 BY MR. DAVIS:

19 Q. Sure. Do you --

20 MR. TRISCHLER: And unless I

21 instruct you not to answer when I

22 lodge an objection, just go ahead

23 and give your answer, Mr. Glover.

24 THE WITNESS: Okay. Thank

Page 40

1 you.

2 BY MR. DAVIS:

3 Q. Do you disagree with the

4 FDA's definition of quality risk

5 management there, which is a proactive

6 means to identify and control potential

7 quality issues during development and

8 manufacturing?

9 A. Well, I disagree with your

10 interpretation that this is a definition.

11 I think the sentence says, "An effective

12 quality risk management approach can

13 further ensure," and those words, I

14 interpret to mean that it may achieve and

15 may provide opportunities to identifying

16 quality and control issues.

17 So a quality risk management

18 program isn't necessarily defined by this

19 sentence. It simply provides an example

20 of an opportunity that it may introduce.

21 Q. If it's something different

22 in some context in your mind, how would

23 you amend this? What would be different

24 in your mind?

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1 A. I just don't think this is

2 intended to be the definition. I'm just

3 simply answering your question.

4 Q. Can you give me your

5 definition?

6 A. I haven't really thought

7 about a definition of quality risk

8 management. But I think again, back to

9 our original conversation, quality risk

10 management by my interpretation is

11 defined 100 different ways for 100

12 different contexts.

13 And so when I've had these

14 discussions with industry partners and

15 regulators, risk management is a process

16 whereby risk is either contemplated,

17 identified, assessed, you know, in

18 various capacities across all walks of

19 the GMP spectrum.

20 And so to give it one

21 definition, I think, does not really

22 effectively do it justice.

23 Q. Well, do you agree that a

24 quality risk management system is

<p>Page 42</p> <p>1 essential to ensuring the quality of 2 Mylan's products? 3 A. I think quality risk 4 management is a part of many, many 5 different quality systems. 6 Q. And one that's essential to 7 ensuring the quality of Mylan's product, 8 correct? 9 MR. TRISCHLER: Objection to 10 form. 11 THE WITNESS: Yeah. Again, 12 I believe it's a part of every 13 quality system. 14 BY MR. DAVIS: 15 Q. If a quality system did not 16 have any risk management controls, would 17 that be an effective quality system in 18 Mylan's opinion? 19 MR. TRISCHLER: Objection to 20 form. Incomplete hypothetical. 21 THE WITNESS: Yeah, I don't 22 think there's such a thing as a 23 quality system without risk 24 management.</p> <p>Page 43</p> <p>1 BY MR. DAVIS: 2 Q. Okay. Can a quality system 3 be GMP compliant if it did not have a 4 risk management system? 5 MR. TRISCHLER: Objection to 6 form. Incomplete hypothetical. 7 THE WITNESS: Again, I'm not 8 even sure we are speaking of the 9 same thing. A quality system is 10 risk management. And so we may 11 wax poetically about this for a 12 long time. 13 The words "risk management" 14 versus the activity of risk 15 management are completely 16 different and semantic. All 17 quality systems are risk 18 management. 19 BY MR. DAVIS: 20 Q. Okay. And so without risk 21 management, you don't have a quality 22 system is what you're saying, correct? 23 A. I'm saying without quality 24 systems, you don't have risk management.</p>	<p>Page 44</p> <p>1 Q. Okay. If you go to the 2 bottom of the page that we're on, there's 3 a section header, "2. Scope." 4 Do you see that? 5 A. Yes. 6 Q. It says, "This guidance 7 provides principles and examples of tools 8 for quality risk management that can be 9 applied to different aspects of 10 pharmaceutical quality. These aspects 11 include development, manufacturing, 12 distribution, inspection, submission 13 review processes throughout the lifecycle 14 of drug substances, drug products, 15 biological/biotechnological products 16 including the use of raw materials, 17 solvents, excipients, packaging and 18 labeling materials in drug products, 19 biological and biotechnological 20 products." 21 Did I read that correctly? 22 A. Yep. 23 Q. Does Mylan agree that the 24 scope of quality risk management should</p> <p>Page 45</p> <p>1 be used across the lifecycle of its drug 2 products and substances used in those 3 products? 4 A. Yes. 5 Q. Does Mylan agree that 6 quality risk management principles should 7 be applied to the use of raw materials 8 and solvents and excipients in addition 9 to API formulations and finished doses? 10 A. Yeah. 11 Q. Okay. Who is responsible at 12 Mylan for actually conducting risk 13 assessments? 14 A. Again, it depends on the 15 context of the risk assessment itself. 16 It can be a large number of people. 17 Q. Is it sort of 18 interdisciplinary? 19 A. Can be. 20 Q. But quality assurance sort 21 of leads the effort when it comes to a 22 risk assessment? 23 A. Not always, but in many 24 cases, yes.</p>
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<p style="text-align: right;">Page 46</p> <p>1 Q. When it comes to potential 2 quality issues that can arise during 3 manufacturing processes, who is involved 4 in a risk assessment to evaluate those 5 potential quality issues? 6 A. It will depend on the stage 7 of the process. So if we're in the 8 development stage, it will be heavily 9 weighted with development scientists. 10 As we go into commercial, 11 then it would be a cross-function of 12 quality, technical services, R&D, 13 production. Again, it's a large list of 14 people that participate in this type of 15 activity. 16 Q. By development, do you mean 17 preapproval? 18 A. Yes. 19 Q. Can effective risk 20 management be done just purely in the 21 abstract, or do you have to actually 22 drill into particular manufacturing 23 processes in order for an effective risk 24 assessment to be done related to those --</p>	<p style="text-align: right;">Page 48</p> <p>1 Tab 6, which will be Exhibit 5. 2 BY MR. DAVIS: 3 Q. Let me know when you've had 4 a chance to review that. 5 A. Okay. Okay. 6 Q. Can you tell me what this 7 document is? 8 A. I can tell by the header 9 that it is an SOP. And I can tell by the 10 numbering convention that it applies to 11 MLL. I'm not positive whether it's a 12 site-level SOP or it could be a corporate 13 level or regionally based SOP. It's not 14 a global SOP. 15 Q. That was going to be my next 16 question, was the numbering convention. 17 MLLCRP. Does that suggest to you that 18 it's corporate for Mylan Laboratories 19 Limited? 20 A. Yeah. Again, I won't 21 know -- I'm hesitant to guess. I can at 22 least tell you that MLL clearly stands 23 for Mylan India. And it's possible that 24 CRP stands for corporate.</p>
<p style="text-align: right;">Page 47</p> <p>1 those processes? 2 A. What do you mean by the 3 abstract? 4 Q. Sure. I mean, could you -- 5 is it sufficient just to have a risk 6 assessment on quality, for example, or do 7 you have to drill into various processes 8 that can affect quality? 9 A. Your question sounds very, 10 very vague. 11 Q. Let me rephrase -- let me 12 rephrase it. 13 When -- how specific does 14 Mylan generally get with its risk 15 assessments? 16 A. It all depends on the topic. 17 So with a more specific question, I might 18 be able to answer your question. 19 Q. Okay. We'll come back to 20 that. 21 (Document marked for 22 identification as Exhibit 23 PL-Glover-5.) 24 MR. DAVIS: I'm introducing</p>	<p style="text-align: right;">Page 49</p> <p>1 But corporate in the way 2 they use that nomenclature, I think, is a 3 grouping of SOPs that are regionally 4 based for the API units. But that would 5 be better answered by someone other than 6 me. 7 Q. So would this quality risk 8 management SOP have applied to Unit 8 9 then? 10 A. It's quite possible. 11 Q. Do you have any reason to 12 think that it would not have applied to 13 Unit 8? 14 A. No. It would be my best 15 guess. 16 Q. Okay. And this is the 17 version as it existed around 2016 based 18 on the dates, correct? 19 A. Yeah. It says effective as 20 of September 2016. 21 Q. Okay. Do you think there's 22 any variability between the quality risk 23 management SOPs for Mylan Laboratories 24 Limited and any of the other Mylan</p>

<p style="text-align: right;">Page 50</p> <p>1 entities out there?</p> <p>2 A. It's quite possible.</p> <p>3 Q. If you look at -- I'm going</p> <p>4 to go through this document, I think, by</p> <p>5 sort of the section numbering. I think</p> <p>6 that'll be easier than page numbering.</p> <p>7 So if you look at Section</p> <p>8 1.1, which is "Purpose."</p> <p>9 It says that the purpose is</p> <p>10 to lay down the procedure for assessing</p> <p>11 the various quality risks associated with</p> <p>12 specific process, system, equipment,</p> <p>13 instrument, in order to evaluate the</p> <p>14 impact on quality of the product or</p> <p>15 services being provided to ensure patient</p> <p>16 safety.</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. Does Mylan agree that</p> <p>20 quality risk management is important to</p> <p>21 ensuring patient safety?</p> <p>22 A. We agree that all quality</p> <p>23 programs are built in a manner that --</p> <p>24 with a goal of ensuring patient safety,</p>	<p style="text-align: right;">Page 52</p> <p>1 for example, does the department heads of</p> <p>2 Unit 8 in quality, do they report up the</p> <p>3 chain of command eventually to you as</p> <p>4 head of global quality?</p> <p>5 A. Eventually, yes.</p> <p>6 Q. How far down the chain of</p> <p>7 command is any particular department head</p> <p>8 at Mylan Unit 8?</p> <p>9 A. From me it would be three</p> <p>10 layers, I believe. I have a vertical</p> <p>11 head that reports to me. And then there</p> <p>12 will be regional or cluster heads, and</p> <p>13 the site heads. So three layers.</p> <p>14 Q. Who is that currently for</p> <p>15 those layers? Do you know their names?</p> <p>16 A. Vertical head?</p> <p>17 The vertical head for API is</p> <p>18 Dr. Antony Gomes.</p> <p>19 Q. Okay. And then the layer</p> <p>20 below him, you described as what?</p> <p>21 Regional --</p> <p>22 A. A cluster head.</p> <p>23 Q. Cluster head?</p> <p>24 A. Yeah. Well, they call it</p>
<p style="text-align: right;">Page 51</p> <p>1 yes.</p> <p>2 Q. Going to Section 2.1,</p> <p>3 "Scope," and this might answer our</p> <p>4 previous question. It says that it shall</p> <p>5 be applicable to all Mylan API sites</p> <p>6 located in India. Does that suggest to</p> <p>7 you that it's applicable to Unit 8?</p> <p>8 A. It does.</p> <p>9 Q. And that would include the</p> <p>10 valsartan API manufactured at Unit 8 that</p> <p>11 was destined for the U.S. market?</p> <p>12 A. Yep.</p> <p>13 Q. Moving to the next section,</p> <p>14 "Responsibility," it says, "Each</p> <p>15 department head is responsible to</p> <p>16 identify the list of process, system,</p> <p>17 equipment, instrument, and assess the</p> <p>18 quality risks involved in their</p> <p>19 respective areas and mitigate them with</p> <p>20 adequate corrective and preventive</p> <p>21 actions."</p> <p>22 Did I read that correctly?</p> <p>23 A. Yep.</p> <p>24 Q. Do the department heads --</p>	<p style="text-align: right;">Page 53</p> <p>1 regional or cluster depending on where we</p> <p>2 are. I think the API uses the</p> <p>3 terminology cluster.</p> <p>4 Q. And who would be the person</p> <p>5 in that role currently reporting to</p> <p>6 Dr. Gomes?</p> <p>7 A. I'm not certain. It may be</p> <p>8 an open position. But I can't say for</p> <p>9 certain.</p> <p>10 Q. Okay. And then this</p> <p>11 department head mentioned in this SOP</p> <p>12 would report to that person?</p> <p>13 A. Correct. Or it could be an</p> <p>14 open position, like I said.</p> <p>15 Q. Okay. This mentions</p> <p>16 corrective and preventive actions. Is</p> <p>17 the acronym for that a CAPA?</p> <p>18 A. Yes.</p> <p>19 Q. So is a CAPA -- so a CAPA</p> <p>20 being both preventive and sort of --</p> <p>21 well, let me rephrase that.</p> <p>22 A CAPA can be made to both</p> <p>23 prevent some kind of quality failure or</p> <p>24 to address the quality failure that</p>

<p style="text-align: right;">Page 54</p> <p>1 happened, correct? It doesn't 2 necessarily have to be responsive, is 3 what I'm getting at, right? 4 A. In the terminology that we 5 apply this word CAPA, they are both 6 conventionally used after something 7 happens. It sounds like you're looking 8 for something else. It probably falls in 9 line with continuous improvement, maybe. 10 Q. Okay. So when Mylan uses 11 the term "CAPA," it's meaning to respond 12 to something as opposed to something else 13 which would be preventing -- you know, 14 identifying a risk and taking measures to 15 prevent it from happening in the first 16 place? 17 A. I would say they're used not 18 exclusively. I just wouldn't want to 19 infer that all proactive measures are 20 CAPAs. Proactive measures can come in a 21 variety of forms. 22 Q. Okay. Let's move down to 23 Section 6 which is "Procedure." 6.1 24 says, "The quality risk assessment shall</p>	<p style="text-align: right;">Page 56</p> <p>1 a particular product basis or would that 2 be, you know, applicable to just, you 3 know, all the products at that site? 4 A. It can literally be 5 anything. 6 Q. Okay. But sometimes it 7 could be applicable to the particular -- 8 a particular product or particular 9 manufacturing process for that product, 10 correct? 11 A. Yeah, it could. 12 Q. There's a scoring system for 13 risk assessments that appears on Page 10 14 of 20. I just want to make sure that I 15 understand this right and whether this is 16 currently how risk assessments are 17 scored. 18 Can you -- can you walk me 19 through what this is discussing in terms 20 of how to score various risks that are a 21 result of a risk assessment? 22 A. This Page 10 just describes 23 a progression of severity and occurrence 24 likelihood. So a higher number means</p>
<p style="text-align: right;">Page 55</p> <p>1 be performed on the specific process, 2 system, equipment, and instrument wherein 3 the anticipated quality risk is 4 involved." 5 Did I read that correctly? 6 A. Yes. 7 Q. This sort of gets to my 8 earlier question about conducting risk 9 assessments in the abstract. 10 Do you read this procedure 11 to instruct the department heads to 12 actually do a risk assessment on the 13 specific -- on specific processes 14 involved in the manufacturing process? 15 A. I think it gives the head of 16 quality the flexibility to apply this to 17 a variety of risk signals. 18 And so, the way I would 19 interpret this is that they would look 20 for any signal that might indicate risk, 21 and then they would apply this procedure 22 or these fundamental, you know, 23 applications to that risk evaluation. 24 Q. And would that be on, like,</p>	<p style="text-align: right;">Page 57</p> <p>1 that there is a higher risk on severity. 2 And a high number on occurrence means 3 it's more likely to occur. 4 Q. Go to the next page, 6.6.25. 5 A. Mm-hmm. 6 Q. And you see there's a little 7 table that has risk level and obtained 8 score. And it has high, medium and low 9 risk and various numbers associated with 10 that. 11 How are those numbers 12 arrived at? 13 A. I think 6.6.24 explains that 14 you multiply the three scores together, 15 and then you'll get one number, and then 16 you just drop it into one of those three 17 categories according to this SOP. 18 Q. Understood. So, for 19 example, if something had a moderate 20 severity, three, a possible likelihood of 21 occurrence, three, and a detection level 22 of not effective or likely to be 23 detected, that would result in a score of 24 27?</p>

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1 A. Right.
2 Q. Okay. And that would be
3 characterized as medium risk, correct?
4 A. Yeah.
5 Q. Okay. When something is
6 characterized as high or medium risk,
7 what's -- what's the next step to take on
8 Mylan's end?
9 A. Again, this is an SOP, so I
10 don't know if they go into that level of
11 detail or not. There's no standard
12 expectations.
13 Q. Are medium -- sorry, I
14 didn't mean to cut you off there. Keep
15 going.
16 A. Page six explains medium.
17 It sounds like there's a communication
18 requirement to the site head.
19 Q. Are you looking at Section
20 6.6.29?
21 A. I was actually looking at
22 6.6.31.
23 Q. Gotcha. Is the goal to --
24 for high and medium risks, is the goal to

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1 implement CAPAs to the point that you
2 arrive at a low risk score?
3 A. I don't think I would say
4 that's specifically the goal, no. I
5 think the idea would be to understand the
6 risk, managing it to an acceptable level.
7 Q. Sure. Through, for example,
8 what this SOP describes as mitigation
9 plans or --
10 A. Sure.
11 Q. -- risk reduction process
12 and procedures?
13 And so even if -- so if you
14 look at -- go back to Page 11 of 20, the
15 detection category. If something is very
16 effective or 100 percent likelihood of
17 detection, it still could be low risk,
18 even if it's almost certain to occur and
19 a fundamental severity of impact,
20 correct, because five times five is 25
21 and that's below 27, correct?
22 A. That's possible.
23 Q. And is the eventual goal of
24 this exercise to always end up in the low

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1 risk category through arriving at, for
2 medium and high risk, initial scores
3 arriving at mitigation plans or risk
4 reduction processes that reduce the
5 scoring to low risk?
6 A. No. I would not say the
7 goal is to find a way to low risk.
8 Q. Explain to me. Why?
9 A. It is quite possible that
10 the risk is intrinsic to the process and
11 that the risk is understood, accepted,
12 and managed acceptably and that the
13 benefit of the product may be greater
14 than the risk.
15 Q. So are you saying in some
16 instances Mylan is okay with medium or
17 high risk?
18 A. I'm saying not only Mylan,
19 that the health authorities and the
20 entire medical community may be okay with
21 that.
22 Q. If there are mitigation --
23 what about if there are mitigation
24 possibilities or risk reduction processes

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1 that can be implemented, should those be
2 implemented --
3 MR. TRISCHLER: Objection to
4 form.
5 BY MR. DAVIS:
6 Q. -- to arrive at a low risk
7 result or are you saying that Mylan still
8 can consider acceptable a medium or high
9 risk?
10 MR. TRISCHLER: Sorry, John.
11 Objection to form.
12 THE WITNESS: I think it's
13 just -- it's got to be more
14 specific than that. It's hard to
15 speculate generally about, you
16 know, everything under the sun.
17 I mean, these -- risk-based
18 decisions are made in a very
19 specific context. We'd have to be
20 speaking about a very particular
21 case.
22 BY MR. DAVIS:
23 Q. Look at 6.6.29. It says,
24 "To scrutinize the risks as high/medium,

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1 identify the person responsible for
2 notification of the risk and the CAPA
3 identified. Low risk shall be considered
4 acceptable."
5 I read that as medium and
6 high risk not being considered
7 acceptable. Do you read that
8 differently?
9 A. I read that as, if it's low
10 risk, you're not required to do anything
11 else to further understand it.
12 If they identified through
13 their signal evaluation that they had a
14 medium or high risk, then the expectation
15 is that they would do all the work to
16 understand it.
17 Q. Regardless --
18 A. But that doesn't necessarily
19 mean that --
20 Q. Regardless, there is an
21 obligation set forth in 6.6.35 to
22 implement CAPAs to reduce the respective
23 risk, correct?
24 MR. TRISCHLER: Objection to

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1 form.
2 THE WITNESS: Again, I think
3 the goal is to identify whatever
4 possibilities exist to reduce the
5 risk. It doesn't necessarily mean
6 that they will arrive at low.
7 BY MR. DAVIS:
8 Q. Okay. In order for a high
9 or medium risk to occasionally be
10 acceptable to Mylan, does that require at
11 least being informed of all the
12 information that goes into that risk
13 level and then accepting that risk?
14 MR. TRISCHLER: Objection.
15 Objection to form.
16 THE WITNESS: Sorry. Could
17 you repeat the question?
18 BY MR. DAVIS:
19 Q. Sure. So you said there is
20 some instances where risk is intrinsic,
21 right? I think that was your word. Do
22 you remember that?
23 A. Yeah.
24 Q. And that it might be

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1 acceptable in some instances for
2 something that might be scored as high or
3 medium risk to -- to be acceptable.
4 Does that presuppose Mylan
5 at least understanding all the
6 information that goes into that -- into
7 that risk designation?
8 MR. TRISCHLER: Objection to
9 form.
10 THE WITNESS: I mean, again,
11 I think Mylan attempts to
12 understand as much as feasible or
13 reasonable for a particular risk
14 evaluation.
15 I don't know that this SOP
16 overrides or requires anything
17 beyond that.
18 BY MR. DAVIS:
19 Q. But if -- if in these
20 situations where Mylan is going to accept
21 a medium or high risk and still move
22 forward with whatever the process we're
23 talking about is -- and I understand that
24 we're talking about this sort of in the

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1 abstract since this is an SOP and it's
2 designed to, you know, be applicable to,
3 you know, any number of quality risk
4 situations that may arise.
5 So with that understanding
6 that this is somewhat of an abstract
7 discussion, don't you agree that for
8 those medium and high risks, that Mylan
9 is willing to accept, that Mylan should
10 at least be knowledgeable as much as it
11 can be about what those risks are?
12 MR. TRISCHLER: Objection to
13 form.
14 THE WITNESS: Yeah, again, I
15 think it really just depends on
16 the case whether I can say yes to
17 that or not. It's really hard to
18 follow the question. It's very
19 abstract.
20 BY MR. DAVIS:
21 Q. I thought it was pretty
22 simple. I mean, don't you agree that
23 Mylan should be -- should educate itself
24 as much as possible as to the various

<p style="text-align: right;">Page 66</p> <p>1 risks involved, especially when we're 2 dealing with situations where Mylan may 3 be willing to accept medium or high risk? 4 MR. TRISCHLER: Objection to 5 form. Objection. Asked and 6 answered. 7 You can answer if you can. 8 THE WITNESS: I don't know 9 how to answer it. I mean, I think 10 I've already said that we -- 11 according to this SOP and our own 12 practices, we attempt to identify 13 risks to the extent possible and 14 feasible. 15 BY MR. DAVIS: 16 Q. Okay. Let's talk about 17 recovered solvents for a little bit, 18 something a little more specific. 19 Do you know when Mylan 20 started engaging with the recovery of 21 solvents for its products? 22 MR. TRISCHLER: Are you 23 talking about valsartan, John? 24 MR. DAVIS: I'm talking</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. TRISCHLER: Okay. 2 BY MR. DAVIS: 3 Q. I'm more interested in the 4 attachment to this e-mail. But I wanted 5 to show you the e-mail for context. 6 Do you see that, the person 7 sending it, Mr. Reddy, is from Unit 8 in 8 his signature line? 9 A. Yep. 10 Q. And do you see that the date 11 is October 17, 2014? 12 A. Yep. 13 Q. And the subject is "Quality 14 Risk Assessment." And it has in 15 quotations, I guess the title: "Usage of 16 recovered solvents in manufacturing of 17 pharmaceutical intermediate API." 18 Do you see that? 19 A. Yeah. 20 Q. Okay. And it has an 21 attachment there. I'm going to show you 22 that next. 23 A. Okay. 24 MR. DAVIS: This is tab</p>
<p style="text-align: right;">Page 67</p> <p>1 about generally. 2 BY MR. DAVIS: 3 Q. Do you know when Mylan 4 generally started using recovered 5 solvents? 6 MR. TRISCHLER: Objection. 7 Beyond the scope, if it's not 8 limited to valsartan. 9 But you can answer if you 10 know. 11 THE WITNESS: I couldn't 12 say. 13 BY MR. DAVIS: 14 Q. Okay. To your knowledge, 15 did Mylan ever conduct a risk assessment 16 regarding quality issues that could arise 17 from Mylan's use of recovered solvents? 18 A. I'm not sure. 19 MR. DAVIS: I'm going to 20 mark -- this is Tab 7, which I'm 21 marking as Exhibit 6. 22 (Document marked for 23 identification as Exhibit 24 PL-Glover-6.)</p>	<p style="text-align: right;">Page 69</p> <p>1 eight. Which is now Exhibit 7. 2 (Document marked for 3 identification as Exhibit 4 PL-Glover-7.) 5 BY MR. DAVIS: 6 Q. Take a moment to review 7 that. And let me know when you're ready 8 to discuss it. 9 (Whereupon, a discussion was 10 held off the record to discuss the 11 technicalities of Zoom speaker 12 positioning.) 13 BY MR. DAVIS: 14 Q. Have you had sufficient time 15 to review the document Mr. Glover? 16 A. Sorry. Just a couple more 17 minutes. 18 Q. Sure. 19 A. Okay. 20 Q. Have you seen this document 21 before? 22 A. I have not. 23 Q. So you would not -- 24 A. I should clarify. I don't</p>

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1 believe I have seen it. I have seen
2 hundreds of documents. And so if I have
3 seen it, I don't recall reading it.
4 Q. Okay. Did you review any
5 documents in preparing for the
6 deposition?
7 A. I reviewed many, yes.
8 Q. About how many?
9 A. I could never guess at how
10 many.
11 Q. This was, to the best of
12 your memory, not one of the ones that you
13 reviewed?
14 A. Correct. It doesn't look
15 familiar to me.
16 Q. I'll note for you this is a
17 draft -- what appears to be a draft risk
18 assessment based on the e-mail, which is
19 the last exhibit, and the fact that this
20 is unsigned.
21 Did you see that it was
22 unsigned when you reviewed it?
23 A. I see it now, yeah.
24 Q. So you haven't seen any

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1 documents that are similar to this that
2 are signed?
3 A. I have not.
4 Q. And so you wouldn't know if
5 this was ever actually signed or another
6 draft of this was eventually signed,
7 would you?
8 A. No, I don't know.
9 Q. Okay. If there was one that
10 was eventually signed off on, who would I
11 go talk to to find that?
12 A. It seems like -- well, I
13 would start with Dr. Antony. But if he
14 hasn't the ability, then whatever this
15 gentleman's name is, maybe would know.
16 MR. TRISCHLER: By
17 Dr. Antony, do you mean Dr. Antony
18 Gomes?
19 THE WITNESS: Dr. Gomes,
20 yeah. These folks report to him.
21 So he would know.
22 MR. TRISCHLER: Sorry, John,
23 I just didn't want there to be
24 confusion on the name.

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1 MR. DAVIS: Sure.
2 BY MR. DAVIS:
3 Q. Under scope, on the -- so
4 you have, you know, the first page, which
5 is a blank signature page. You have the
6 second page, which is the table of
7 contents.
8 The first substantive page
9 has a Section 2.0, which is "Scope."
10 A. Okay.
11 Q. It says that, "The scope of
12 the risk assessment is applicable to the
13 usage of recovered solvents for
14 manufacturing of pharmaceutical
15 intermediate API Unit 8 Mylan
16 Laboratories Limited."
17 Did I read that right?
18 A. Yep.
19 Q. And so that would include
20 valsartan API?
21 A. Yeah.
22 Q. Including valsartan API
23 destined for the U.S. market, correct?
24 A. Yes.

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1 Q. Is it Mylan's standard
2 practice to sign off on risk assessments
3 like this one if they're actually
4 conducted to completion?
5 A. Normally I would think, yes,
6 unless there was some decision not to
7 finish it.
8 Q. Okay. And once it's signed
9 off on, if it ever was signed off on, it
10 says below that in Section 3, that once
11 the risk assessment is closed, it shall
12 be reviewed for adequacy once in three
13 years. Is that a standard practice
14 across Mylan?
15 A. No. I don't think we have a
16 global standard practice on that. That
17 would be established within their local
18 SOPs.
19 Q. Okay. So again, on Pages 4
20 and 5, you see again sort of what we saw
21 in the SOP, which is likelihood of the
22 risk occurring scoring, severity of
23 impact scoring, and the existing
24 mitigation controls scoring.

<p style="text-align: right;">Page 74</p> <p>1 Do you see that?</p> <p>2 A. Yep.</p> <p>3 Q. And then there's a table.</p> <p>4 This is a little different from the SOP</p> <p>5 that we looked at. But there is a table</p> <p>6 that has likelihood and severity, and the</p> <p>7 sort of eventual risk scoring, correct?</p> <p>8 Do you see that?</p> <p>9 A. Yep. I'm assuming you're on</p> <p>10 Page 7 at this point?</p> <p>11 Q. I'm on page -- let's see.</p> <p>12 I'm on page -- there's a numbering at the</p> <p>13 top right corner.</p> <p>14 Do you see that?</p> <p>15 A. Yeah, yeah.</p> <p>16 Q. I'm on page Number 5.</p> <p>17 A. Oh, I'm sorry. I got ahead</p> <p>18 of you.</p> <p>19 Q. So do you see that? Do you</p> <p>20 read that bottom table on Page 5 as sort</p> <p>21 of the outcome scoring of the risk</p> <p>22 assessment?</p> <p>23 A. Yeah, that's sort of a</p> <p>24 depiction of the matrix. I don't think</p>	<p style="text-align: right;">Page 76</p> <p>1 high risk, that additional controls have</p> <p>2 to be implemented, at least according to</p> <p>3 this chart?</p> <p>4 A. I think this is the</p> <p>5 instruction they've given the people</p> <p>6 executing this, yes. But it doesn't</p> <p>7 preclude the possibility that we may need</p> <p>8 to make an exception.</p> <p>9 Q. But the bottom line is that</p> <p>10 if something, you know, according to</p> <p>11 these instructions, if the outcome of</p> <p>12 this risk assessment is medium or high</p> <p>13 risk, that more work had to be done?</p> <p>14 A. At least attempted to be</p> <p>15 done, yes.</p> <p>16 Q. Okay. And then the next</p> <p>17 page is -- do you agree with me that's</p> <p>18 where, like, the actual risk assessment</p> <p>19 starts?</p> <p>20 A. Yes.</p> <p>21 Q. So the very first one, which</p> <p>22 is S Number 1, under the description of</p> <p>23 risk it reads, "Usage of recovered</p> <p>24 solvents in manufacturing process." And</p>
<p style="text-align: right;">Page 75</p> <p>1 that's intended to be -- this particular</p> <p>2 risk assessment output, my understanding</p> <p>3 is this is an example.</p> <p>4 Q. Correct. That's how I read</p> <p>5 it too.</p> <p>6 And then the sort of next</p> <p>7 page after that, Page 6, is sort of the</p> <p>8 recommended actions to take based on the</p> <p>9 scoring matrix, correct?</p> <p>10 A. Right.</p> <p>11 Q. And then for, you know, no</p> <p>12 and low risk, you know, no risk is, you</p> <p>13 know, no additional risk control measures</p> <p>14 are needed. Low risk is additional</p> <p>15 controls may be considered. Medium risk</p> <p>16 is additional controls CAPAs must be</p> <p>17 implemented. And then high risk is, you</p> <p>18 know, must be reduced to at least medium</p> <p>19 risk.</p> <p>20 Did I -- did I read all that</p> <p>21 correctly?</p> <p>22 A. That's what it says.</p> <p>23 Q. So the bottom line of this</p> <p>24 is basically, if there is a medium or</p>	<p style="text-align: right;">Page 77</p> <p>1 then it says, "Risk factors, Number 1,</p> <p>2 contamination; Number 2, impurities."</p> <p>3 Do you see that?</p> <p>4 A. Yep.</p> <p>5 Q. And that's -- those are the</p> <p>6 very first risks that are identified,</p> <p>7 right?</p> <p>8 A. Yep.</p> <p>9 Q. If the risk factors -- the</p> <p>10 main risk factors are contamination or</p> <p>11 impurities of the API through the use of</p> <p>12 recovered solvents, what would be some</p> <p>13 logical risk management activities that</p> <p>14 Mylan might take to reduce that risk?</p> <p>15 A. Well, you can see the choice</p> <p>16 they made, which was to execute the test</p> <p>17 on every incoming batch. So on the right</p> <p>18 side, the additional control is to apply</p> <p>19 the analytical testing required for fresh</p> <p>20 solvent and apply the exact same specs</p> <p>21 and methods to the recovered.</p> <p>22 Q. Gotcha. So doing</p> <p>23 impurity -- basically testing for</p> <p>24 impurities?</p>

1 A. Whatever the registered and
2 approved specifications were for the
3 incoming solvent, they applied both the
4 same to the fresh and the recovered.

5 Q. If the -- if the main risks
6 are contamination and impurities, would
7 it make sense to test for impurities?

8 A. Not necessarily. There are
9 other ways of testing material like that,
10 and they may have tested it for potency
11 or -- I mean, purity itself may be
12 constituting a total area type of
13 calculation. It might be an overall
14 content of the analyte or the solvent of
15 interest. There's a bunch of ways to
16 evaluate the overall impurity of the
17 material. That test method would have
18 been disclosed and agreed upon to some
19 level with the health authorities.

20 Q. Well, I wasn't talking about
21 testing for purity though. I was talking
22 about -- because the description of the
23 risk says, you know, that the top risk
24 factors are contamination and impurities.

1 So my question is, would it
2 make sense to test for impurities if
3 those are the risks?

4 A. Yeah, again, not
5 necessarily. You know, it's a standard
6 practice, and has been a standard
7 practice to use purity itself as an
8 acceptable level. And the inference
9 being if you have sufficient purity, then
10 you have reduced the total impurities to
11 an acceptable level.

<div>Page 82</div> <div>1 [REDACTED]</div> <div>2 [REDACTED]</div> <div>3 [REDACTED]</div> <div>4 [REDACTED]</div> <div>5 [REDACTED]</div> <div>6 [REDACTED]</div> <div>7 [REDACTED]</div> <div>8 [REDACTED]</div> <div>9 [REDACTED]</div> <div>10 [REDACTED]</div> <div>11 [REDACTED]</div> <div>12 [REDACTED]</div> <div>13 [REDACTED]</div> <div>14 [REDACTED]</div> <div>15 [REDACTED]</div> <div>16 [REDACTED]</div> <div>17 [REDACTED]</div> <div>18 [REDACTED]</div> <div>19 [REDACTED]</div> <div>20 [REDACTED]</div> <div>21 [REDACTED]</div> <div>22 [REDACTED]</div> <div>23 [REDACTED]</div> <div>24 [REDACTED]</div>	<div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div> <div>[REDACTED]</div>
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1 are back on the record.
2 BY MR. DAVIS:
3 Q. We were discussing
4 Exhibit 7, I believe. Is it Exhibit 7?
5 A. Yes.
6 Q. Okay. We were discussing
7 Exhibit 7 when we took a break. Let me
8 ask you, Mr. Glover, is there anyone else
9 in the room with you other than you and
10 Mr. Trischler?
11 A. We have another counsel with
12 us.
13 Q. Who is that person?
14 A. Bradley Matta.
15 Q. Is that a Mylan inhouse
16 lawyer?
17 A. Yes.
18 MR. TRISCHLER: And just to
19 be clear, John, Jason Reefer is in
20 and out of the deposition. But
21 he's not here right now. That's
22 why Mr. Glover only indicated
23 Brad's presence.
24 MR. DAVIS: I think, Clem,

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1 we agreed that if any other
2 counsel were going to be in the
3 room, that they would have their
4 screens up.
5 Is that possible for
6 Bradley.
7 MR. TRISCHLER: Sure. I
8 thought that -- I didn't realize
9 they were not. Can you log on to
10 the --
11 Are you logged onto the
12 Zoom, Brad?
13 MR. MATTA: No. I'll get
14 the information and log in.
15 MR. TRISCHLER: Let me -- do
16 you want to give me two minutes to
17 give him the login information?
18 MR. DAVIS: Sure, that's
19 fine.
20 THE VIDEOGRAPHER: Counsel,
21 do you want to go off the record?
22 MR. DAVIS: Sure. Just for
23 two minutes.
24 MR. TRISCHLER: Sure, we

Page 88

1 can.
2 THE VIDEOGRAPHER: The time
3 is 10:40 a.m., and we're off the
4 record.
5 (Short break.)
6 THE VIDEOGRAPHER: The time
7 right now is 10:45 a.m., and we're
8 back on the record.
9 BY MR. DAVIS:
10 Q. Okay, Mr. Glover. As we
11 mentioned we were -- we went off the
12 record while we were in the midst of
13 discussing Exhibit 7, which is this draft
14 risk assessment on the use of recovered
15 solvents, correct?
16 A. Yeah.
17 Q. Did you review this document
18 further during the break?
19 A. I did not.
20 Q. Okay. So when we left off,
21 you -- and if I'm mischaracterizing what
22 you're saying, I'm sure you or Clem will
23 let me know. But you were saying that
24 the nitrosamine contamination, in your

Page 89

1 view, was not a quality failure of the
2 product?
3 A. No. I think I was saying
4 that the way this words -- it says
5 carryover recovery -- recovering the
6 intended solvent lead to quality failure
7 of the product.
8 I interpret that to be
9 failure of the product to meet
10 specifications, and those specifications
11 being established within the DMF, in this
12 case the solvent specifications being the
13 incoming test requirement.
14 I don't think nitrosamine
15 would have caused it to fail its
16 specifications --
17 Q. The product --
18 A. -- according to what I had
19 read --
20 Q. Does the product here refer
21 to the API, the way you read it?
22 A. Well, or the solvent. The
23 solvent itself will also have limits
24 applied to the testing for its incoming

Page 90

1 evaluation.

2 Q. Let's just take -- remove

3 the specification discussion for a second

4 and bear with me.

5 Would Mylan agree that the

6 carryover of volatile -- of organic

7 volatile compounds while recovering the

8 intended solvent led to contamination and

9 impurities in the case of valsartan?

10 MR. TRISCHLER: Objection to

11 form. Objection. Beyond the

12 scope.

13 You can answer again.

14 THE WITNESS: Again, I

15 didn't quite follow it. You'll

16 have to repeat it, and then I can

17 try.

18 BY MR. DAVIS:

19 Q. Sure. Sure.

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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1 your individual capacity.

2 Would you agree that the

3 root cause investigation that was

4 conducted by Mylan found that the

5 carryover of organic volatile compounds

6 while recovering o-xylene led to

7 contamination and impurities in the

8 valsartan API and finished dose?

9 A. I think you're missing a

10 couple steps based on my study of the

11 investigation.

12 It sounds like that's a

13 general way to describe it. But there

14 were, you know, basically side reactions

15 of trace elements that were in those

16 carryovers that eventually manifested in

17 that, you know, generation of nitrosamine

18 impurity. But it wasn't like primary

19 carryover versus, you know, the reagents

20 being used. It was byproducts of the

21 reagents and trace, you know, presences

22 within the carryover solvents themselves.

23 So I don't know, it seems

24 like you are simplifying it a little

Page 92

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 MR. TRISCHLER: That's a

15 different question.

16 BY MR. DAVIS:

17 Q. -- inaccurate about that?

18 MR. TRISCHLER: That's a

19 different question.

20 Object to form as beyond the

21 scope.

22 He's not been designated on

23 this subject matter. Also

24 mischaracterizes prior testimony.

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1 You can answer it again.

2 THE WITNESS: I'll have to

3 hear the question again. I'm

4 sorry.

5 MR. DAVIS: Can you read the

6 question back.

7 MR. HONIK: You know,

8 respectfully, there should not be

9 speaking objections. It's making

10 it very difficult for the witness

11 to hear the question and respond

12 promptly.

13 So I would ask respectfully

14 that you defer from making a

15 speaking objection.

16 MR. TRISCHLER: I don't

17 think I made one. But I

18 understand what -- I understand

19 what the rules are, Ruben, and I

20 follow them.

21 MR. DAVIS: Michelle, can

22 you read back my previous

23 question.

24 (Whereupon, the court

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1 reporter read back the requested
2 portion of testimony.)
3 MR. TRISCHLER: Objection.
4 Beyond the scope.
5 MS. DAVIS: This is D'Lesli
6 Davis. I just want to state real
7 quickly there's a difference in
8 opinion from Mr. Davis when he is
9 defending depositions and what --
10 MR. DAVIS: Come on,
11 D'Lesli. This is -- this is --
12 MS. DAVIS: No, I just --
13 no, I have to put it on the
14 record.
15 MR. DAVIS: There's a
16 question pending, D'Lesli.
17 MS. DAVIS: Mr. Davis, let
18 me speak. Let me speak.
19 My objection is that
20 Mr. Davis, when he is defending
21 the depositions, has routinely
22 engaged in speaking objections. I
23 appreciate what Mr. Honik said. I
24 want the record to note that there

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1 is an inconsistency in approach by
2 plaintiff's counsel generally and
3 by Mr. Davis at this deposition
4 when he is taking it versus when
5 he's defending.
6 MR. DAVIS: D'Lesli, you're
7 not defending the witness.
8 MR. HONIK: There's a
9 question pending. Let the witness
10 answer it, please.
11 MR. DAVIS: Do you want the
12 question read back again,
13 Mr. Glover.
14 THE WITNESS: I think what
15 I'm struggling is with the use of
16 the word "carryover."
17 And so maybe you can read it
18 again. But my problem with the
19 use of the word "carryover" is
20 that the generality of
21 carryover -- and maybe you're
22 thinking of it that way.
23 When I think of carryover, I
24 think of one particular thing

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1 carrying over.
2 And it wasn't the carryover.
3 It was something inside the
4 carryover that was unanticipated
5 that eventually reacted with a
6 side product of some other
7 reaction.
8 And eventually, yes, that
9 led to the generation of the
10 nitrosamine.
11 BY MR. DAVIS:

■ [REDACTED]

■ [REDACTED]

<div>1</div> <div>[REDACTED]</div>	<div>Page 98</div> <div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

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[REDACTED]

7 MR. DAVIS: I'm going to
8 mark Tab 58 as Exhibit 10.

9 (Document marked for
10 identification as Exhibit
11 PL-Glover-10.)

12 BY MR. DAVIS:

13 Q. Do you have that in front of
14 you?

15 A. I do.

16 Q. It's a 50-page document.
17 So -- and I really only want to ask about
18 one part or one statement in it.

19 But let me just ask of you,
20 does this look like a document that
21 you've ever seen?

22 A. I can't say for certain. It
23 doesn't look familiar.

24 Q. Okay. I'll represent to you

[REDACTED]

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1 that the metadata for this document says
2 that it was created on December 14th,
3 2019, and that the file name is "Unit 8
4 Risk Review Report 28/11/19.PDF."

5 And I'm going to take you
6 down to Page 5. There's a numbering
7 convention at the bottom right corner.
8 Page 5 of 49. Section D, evaluation of
9 risk of general raw materials used for
10 valsartan manufacturing process.

11 Do you see that?

12 A. Yeah.

13 Q. Then if you go down to Page
14 8 of 49, you'll see triethylamine.

15 A. Okay.

16 Q. And then there's a column
17 called "Evaluation of Risk Through
18 Chemistry."

19 Do you see that?

20 A. Yeah.

[REDACTED]

[REDACTED]

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1 personal capacity.
2 THE WITNESS: Do I have to
3 answer again?
4 MR. TRISCHLER: Yes.
5 THE WITNESS: Okay. As I
6 said before, I think the
7 diethylamine was only identified
8 as a trace element to
9 triethylamine, which was also
10 identified as a trace element,
11 coming over in the organic layer.
12 It did not react with sodium
13 nitrite or HCl. It reacted with a
14 side reaction which generated
15 nitro -- that's my understanding
16 of the root cause of why
17 nitrosamine was formed.
18 BY MR. DAVIS:
19 Q. Are sodium nitrite and
20 hydrochloric acid nitrosating agents?
21 A. That would be beyond my
22 expertise as a chemist. I can't tell
23 you. But I don't believe so.
24 Q. You'll see in the column

Page 107

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 Do you see that?
7 A. Yeah.
8 Q. Do you know which of these
9 procedures was used for the recovery of
10 o-xylene?
11 A. I do not.
12 Q. Can you explain to me just
13 in general terms the difference between
14 them?
15 A. I'd be hesitant to try. I'm
16 not really familiar with them.
17 Q. Okay. You're not a chemist,
18 are you?
19 A. I am.
20 Q. Do you have any graduate
21 degrees?
22 A. I have a BS in chemistry.
23 Q. Where did you get that from?
24 A. West Virginia University.

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1 Q. And you spent a few years
2 as -- working in chemistry for Mylan at
3 the beginning of your career at Mylan?
4 A. I did.
5 Q. How long ago was that?
6 A. 1997.
7 Q. Okay. Would you call
8 yourself -- do you have any current roles
9 that involve chemistry?
10 A. I mean, evaluation of work
11 that I do involves chemistry, but I don't
12 actually work in the chemistry lab
13 anymore.
14 Q. And it's been how many years
15 since you did work in the chemistry lab?
16 A. I don't know. Approximately
17 15.
18 Q. Okay. There's a reference
19 under "in process distillation" there to
20 an MBPR. Can you tell me what that is?
21 A. A master batch production
22 record.
23 Q. Do recovered solvents have a
24 master batch production record that's

Page 109

1 unique to them?
2 A. I believe so.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 Q. How would you know that?
24 A. We reviewed it as part of

Page 110

1 preparation.

2 MR. TRISCHLER: Just as a

3 word of caution, Mr. Glover, you

4 don't have to disclose things that

5 you reviewed with me.

6 THE WITNESS: Oh sorry.

7 MR. TRISCHLER: That would

8 be privileged. I understand. But

9 you know, I don't think John wants

10 you to disclose and identify

11 things that you reviewed with me.

12 BY MR. DAVIS:

13 Q. Well, I certainly don't want

14 you to disclose communications that you

15 had with counsel. However, I do think

16 I'm entitled, especially since you're a

17 30(b)(6) witness, to know what documents

18 that you reviewed to prepare for the

19 deposition. But, you know, we can --

20 MR. TRISCHLER: That's a

21 different -- that's a different

22 question. And I don't want to

23 get -- I'm not trying to get --

24 MR. DAVIS: We don't have to

Page 111

1 have that fight now.

2 MR. TRISCHLER: -- down a

3 rabbit hole, John.

4 MR. DAVIS: Yeah.

5 MR. TRISCHLER: But I think

6 there's a difference between what

7 he reviewed for the deposition and

8 things that I may have reviewed

9 with him.

10 MR. DAVIS: Sure, okay. All

11 right. That's fair. And if I --

12 BY MR. DAVIS:

13 Q. If, Mr. Glover, I ask you

14 about those documents that you reviewed

15 to prepare, do you follow the distinction

16 that counsel is making?

17 No? Okay. We'll cross

18 that -- we'll cross that bridge when we

19 get there.

20 So on the end column on

21 Exhibit 7, and I believe you referred to

22 this earlier, that there should be a

23 recovered solvent comparison with

24 merchant solvent specification.

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1 Do you see that?

2 A. Yes.

3 Q. Okay. How would -- how

4 would such a comparison potentially

5 address contamination or impurities

6 resulting from the carryover of volatile

7 organic compounds leading -- in the

8 recovered solvent process?

9 MR. TRISCHLER: Objection to

10 form.

11 THE WITNESS: Yeah, I don't

12 quite follow the question. But

13 the comparison is meant to

14 establish that both the recovered

15 and the virgin solvent achieve the

16 same level of quality, or the same

17 level of, you know, critical

18 quality attributes established

19 within the spec.

20 It meets the same standard

21 established within that

22 registration.

23 BY MR. DAVIS:

24 [REDACTED]

Page 113

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 114

1 [REDACTED]
2 BY MR. DAVIS:
3 Q. Are you aware of any
4 regulatory agency telling Mylan it
5 shouldn't do that?
6 A. Shouldn't do what?
7 Q. Shouldn't just test
8 recovered solvents for purity as opposed
9 to also testing them for impurity?
10 A. I'm not aware of any
11 regulatory body telling us, no.
12 We share these
13 specifications with the regulatory body
14 when we registered the DMF.
15 Q. That's assuming that
16 recovered solvents are part of the DMF,
17 correct?
18 A. Yes.
19 Q. And if recovered solvents
20 are not part of the DMF, then no
21 specification would be included in the
22 DMF for those recovered solvents,
23 correct?
24 A. The virgin solvent spec

Page 115

1 would. And in this case, obviously we
2 established that they would be identical.
3 Q. You've established that
4 recovered solvents and virgin solvents
5 would be identical?
6 A. They would be tested to the
7 identical specification. I thought we
8 were talking about the specification.
9 Q. Gotcha. Okay. I just
10 wanted to clarify that.
11 If you go to Page 11, you'll
12 see the conclusion.
13 The conclusion was low risk,
14 according to this, right?
15 A. Yes.
16 Q. Okay. And that meant, based
17 on what we looked at above, in terms of,
18 you know, the action items to take per
19 whoever was instructing these individuals
20 to do this risk assessment, low risk
21 meant that, you know, follow-up or
22 additional controls were not required to
23 be put in place, correct?
24 A. Correct.

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1 Q. Okay. Who do you think that
2 person would be? Would that be Dr. Gomes
3 for this risk assessment to talk to about
4 -- you mentioned -- like there's a "they"
5 I think you threw out when you were
6 talking about the instructions that were
7 given to these folks. Would that be Dr.
8 Gomes?
9 A. Instructions? I'm sorry.
10 You're losing me.
11 Q. Sure. I'm referencing what
12 we were talking about earlier with the
13 scoring system here, which is on Pages 4
14 and 5. And you mentioned that, you know,
15 these individuals in the e-mail all
16 report up to Dr. Gomes.
17 Is Dr. Gomes the person that
18 I should talk to about this risk
19 assessment, or is there somebody else
20 that you might think would be more
21 factually knowledgeable about this?
22 A. No, I think he'd be fine. I
23 mean, I don't have a better name for you.
24 Q. Okay. Do you know whether,

Page 117

1 prior to recall, Mylan ever did a risk
2 assessment specifically regarding its use
3 of recovered solvents in the manufacture
4 of valsartan?
5 A. Say that again. I'm sorry.
6 I'm getting confused with the difference
7 between what you just asked me and what
8 we just reviewed. Didn't we just review
9 a risk assessment?
10 Q. Sure. But that's not unique
11 to valsartan, correct? Exhibit --
12 A. It not particularly
13 exclusive of valsartan either, right?
14 Q. Sure. And I -- exactly.
15 But I'm asking a different
16 question, slightly, which is: Did Mylan
17 ever do a risk assessment specifically
18 for recovered solvents that were used in
19 valsartan?
20 A. I'm not sure. I haven't
21 seen one, if there is one. At least I
22 don't think I have.
23 [REDACTED]
24 [REDACTED]

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11 BY MR. DAVIS:

12 Q. Yeah. I mean, you're

13 designated on this topic, are you not?

14 Did you do any investigation to see if

15 such activities were done?

16 A. Not specifically the way

17 you're asking it, no.

18 Q. Okay. What documents did

19 you review to prepare for this topic,

20 namely, you know, evaluating the risk of

21 the solvents used in the manufacture of

22 valsartan?

23 A. The only thing that I can

24 think of that -- I mean, I -- it's so

Page 119

1 hard for me to reflect and memorize

2 everything I read.

3 I read the responses to our

4 483s and warning letters. And there was

5 discussion about that topic in there, I

6 think.

7 The DMF deficiency responses

8 were other documents that had discussions

9 about that.

10 Q. So you did not investigate

11 whether Mylan, prior to recall, actually

12 evaluated the risks of using recovered

13 solvents in valsartan specifically?

14 MR. TRISCHLER: Objection to

15 form.

16 THE WITNESS: I don't recall

17 asking for that, no.

18 BY MR. DAVIS:

19 Q. Who would you have asked for

20 that?

21 A. It would have been

22 Dr. Gomes, likely, if I was looking for

23 something like that. But I don't recall

24 asking for it.

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1 MR. DAVIS: Okay. I'm going

2 to mark another exhibit. This is

3 Tab 10, which I'm marking as

4 Exhibit 11.

5 (Document marked for

6 identification as Exhibit

7 PL-Glover-11.)

8 MR. DAVIS: And I'm going to

9 mark Tab 11 also, which is an

10 attachment to that e-mail, as

11 Exhibit 12.

12 (Document marked for

13 identification as Exhibit

14 PL-Glover-12.)

15 BY MR. DAVIS:

16 Q. Let's start with the e-mail.

17 A. Okay.

18 Q. So do you see that the dates

19 on this e-mail are December 31st, 2018?

20 A. I do.

21 Q. Okay. And then if you look

22 at Tab 11, which is exhibit -- which

23 exhibit is that again? What did we mark

24 that as?

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1 A. 12.

2 Q. 12. If you look at the

3 attachment, which is Exhibit 12, do you

4 see that that's another unsigned draft of

5 this quality risk assessment on usage of

6 recovered solvents?

7 A. Yep.

8 Q. Does it look similar to the

9 one that we looked at earlier?

10 A. It looks like it has similar

11 format, yes.

12 Q. December 31st, 2018, is

13 after the recall, correct?

14 A. Yes.

15 Q. Do you see that this one --

16 this version is also unsigned?

17 A. Yes.

18 Q. Go to Page 7. Okay. Do you

19 see that the risk severity has been

20 denoted as severe?

21 A. Yeah.

22 Q. That's a change from

23 Exhibit 7, correct, where the risk

24 severity was only denoted as moderate?

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1 A. I don't see a severity in
2 Section 1 of the original document.
3 Q. If you go to Page 7 of the
4 original document, Tab -- sorry,
5 Exhibit 7?
6 A. Oh, I'm sorry. Yeah, you're
7 right.
8 Q. So do you see that it's been
9 changed from moderate to severe?
10 A. Yes.
11 Q. If you go back to Page 4 on
12 Exhibit 12, which is the second version
13 of this risk assessment, you'll see that
14 the severity of impact table defines
15 severe as, "May cause permanent damage.
16 Additional controls have to be in place
17 before work commences"?
18 A. Yes, I see it.
19 Q. Okay. Who would I talk to
20 about why that risk severity designation
21 was changed? Would that be Dr. Gomes as
22 well?
23 A. I mean, he's probably the
24 most familiar with it. Obviously this

Page 123

1 risk assessment was generated after the
2 investigation and the recall, so I'm sure
3 they re-visited several aspects of it.
4 Q. The far right column has
5 some additional language in it as well,
6 on Page 7 of Exhibit 12. It says,
7 "Volatile organic compounds that can be
8 contributed from the parent manufacturing
9 process shall be considered in designing
10 the recovery procedure for the solvents."
11 Do you see that?
12 A. Okay.
13 Q. What does that mean?
14 A. Again, I didn't draft it.
15 I'm not sure. I can only guess that
16 they're trying to add some additional
17 controls to anticipate the learnings from
18 this investigation.
19 Q. How can you -- how can you
20 consider volatile organic compounds that
21 can be contributed from the parent
22 manufacturing process without looking at
23 the -- looking at it on a
24 product-by-product basis?

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1 A. That's exactly how I
2 interpret this risk assessment to state,
3 that if, in fact, you're going to use
4 recovered solvents, that you have to
5 consider that on a product basis.
6 Q. Okay. Can you explain why
7 the metadata says that this second
8 version of this risk assessment that
9 we're looking at, Exhibit 12, was also
10 created in 2014?
11 A. Can you tell me what you
12 mean by metadata?
13 Q. Sure. That's the
14 information that comes with a document
15 that has sort of, you know, file names,
16 dates, unique hash identifiers, et
17 cetera.
18 The metadata that was
19 produced to us by Mylan says that this
20 document was also created in late 2014.
21 Do you have any idea why it
22 was being recirculated in 2018 and when
23 the text of that document was changed in
24 the ways that we just went through?

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1 MR. TRISCHLER: Objection to
2 the extent it's beyond the scope.
3 John, is the metadata you're
4 asking him about what's on
5 Exhibit 11? I think that might
6 help the witness to understand.
7 MR. DAVIS: It's not,
8 unfortunately.
9 MR. TRISCHLER: Oh.
10 MR. DAVIS: The --
11 Exhibit 11 is an e-mail from
12 December 31st, 2018.
13 BY MR. DAVIS:
14 Q. However I'll represent to
15 you, Mr. Glover, that the attachment,
16 Exhibit 12, has a date stamp of 2014.
17 And my question is do you
18 have any idea why this document was being
19 recirculated after the recall and when
20 those changes to the text were made? And
21 if the answer is no, you don't know, then
22 that's fine.
23 MR. TRISCHLER: I'll just
24 object to the extent that it's

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1 beyond the scope of the
2 designation.
3 THE WITNESS: I don't
4 understand what he's looking at.
5 I mean, where do you see
6 2014 date stamping on the document
7 from '18?
8 BY MR. DAVIS:
9 Q. Sure. There's a metadata
10 that comes with the production files that
11 we get from Mylan.
12 A. I don't know what that
13 means.
14 Q. Yeah, and it's fine if you
15 don't know what that means. I'm just
16 going to represent to you that the date
17 of the document in those electronic
18 metadata fields say it was from 2014.
19 And so my question is, do
20 you know why this was being recirculated
21 in late 2018 and when those changes to
22 the text were made to it?
23 A. I mean, I'm not an IT
24 expert. I have no idea why that would be

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1 that way.
2 I would imagine that if
3 someone were writing a revision to this
4 risk assessment, they would start by
5 using the original data file and then
6 just updating that and saving that as a
7 new file, rather than waste time
8 generating all this from scratch.
9 And so in your terms of
10 metadata, I don't know if that somehow
11 captures the original file nomenclature.
12 But that's just pure unadulterated
13 speculation.
14 Q. Sure. And I don't want you
15 to speculate.
16 Maybe look at the -- if you
17 have Exhibit 12 in front of you. Look at
18 the top right corner. You'll see Report
19 Number RAR/QAD/GEN/014/14.
20 A. Right.
21 Q. Do those 14s refer to the
22 year? Do either of those 14s refer to
23 the year?
24 A. I don't know. But if they

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1 do, and if their local process is to
2 issue revisions and then simply version
3 it, that's always possible. We'd have to
4 interview Dr. Antony. I think he'd have
5 a better understanding of the local
6 change process.
7 MR. DAVIS: Okay. I'm
8 marking Tab 12 as Exhibit 13.
9 (Document marked for
10 identification as Exhibit
11 PL-Glover-13.)
12 BY MR. DAVIS:
13 Q. Let me know when you've had
14 a chance to review that.
15 MR. TRISCHLER: I haven't
16 even given it to him yet, John,
17 because I think I've lost the
18 extra copy, so we only got one
19 copy of it.
20 But let me -- here, let me
21 just put a mark on that so I know
22 what it is.
23 Okay. He has it now.
24 BY MR. DAVIS:

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1 Q. Let me know when you've had
2 a chance to review that, Mr. Glover.
3 A. Okay.
4 Q. Do you see that this e-mail
5 chain is -- takes place in September and
6 early October, I guess, of 2012?
7 A. Yeah.
8 Q. And that the subject of the
9 e-mail chain is "Valsartan recovery
10 solvents/materials"?
11 A. Yeah.
12 Q. Okay. Is this around the
13 time that Mylan made a decision to use
14 recovered solvents in valsartan?
15 A. Again, I can't remember. I
16 think we even covered that here today,
17 and I can't remember exactly when we
18 decided to use it. But, yes, I think
19 it's around that time.
20 Q. Okay. And in fact, the very
21 first e-mail of that chain on Page 3 says
22 that, "The following is a proposal for
23 the usage of recovered solvents of the
24 Unit 3 VSN process and the Unit 8 VST

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1 process."
2 Do you see that?
3 A. Yeah.
4 Q. Was VSN the old process code
5 for valsartan that was developed by
6 Matrix?
7 A. I believe so.
8 Q. Okay. Was VSN ever
9 commercialized or did that change?
10 A. I'm not certain.
11 Q. Okay. If you go up to
12 Page 1 again of this e-mail, the e-mail
13 is from Sashant Pokhariyal. And forgive
14 me if I butcher the name.
15 Do you know him?
16 A. I do not.
17 Q. Okay. He's asking if there
18 are any concerns to consume recovered
19 solvents.
20 Do you see that?
21 A. Yes.
22 Q. Is that a question that
23 Mylan's quality department ever looked
24 at?

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1 A. I think we've already looked
2 at a risk assessment from 2012 that said
3 they did evaluate recovered solvents.
4 Q. Well, that was a draft,
5 unsigned one, correct, the one we
6 reviewed?
7 A. Yeah, it's the only evidence
8 that I have that it happened. So I don't
9 know of any other exercises.
10 Q. What was your role in 2012
11 around the time that this e-mail was
12 written?
13 A. I think I was just
14 transitioning out of head of quality at
15 Morgantown into head of North America
16 quality.
17 Q. Okay. In your time in
18 quality between, you know, the time of
19 this e-mail and up to pre-recall, were
20 there any discussions that you
21 participated in regarding concerns about
22 using recovered solvents?
23 A. No.
24 Q. The proposal to use

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1 recovered solvents in valsartan was
2 eventually adopted, right?
3 A. Yeah.
4 Q. To the point that pretty
5 much all batches of valsartan that were
6 intended for the U.S. market were
7 manufactured using recovered solvents?
8 MR. TRISCHLER: Objection to
9 the form.
10 THE WITNESS: I'm not
11 certain. I haven't done that type
12 of a review.
13 BY MR. DAVIS:
14 Q. Sticking with this e-mail
15 chain, do you see in the e-mails on Page
16 2 and on Page 1 there's references to
17 change control forms?
18 A. Yes.
19 Q. What's a change control
20 form?
21 A. It's a documented process by
22 which you propose a change and gain
23 approval.
24 Q. Internal approval or

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1 external approval?
2 A. It can be both. The change
3 control process is internal. But if it
4 coincides with a requirement to notify
5 and gain outside approval from a health
6 authority, then that is part of the
7 process also.
8 Q. In that same e-mail from
9 Sashant, he says, "A clearance is in
10 place to consume the recovered solvents
11 in valsartan, then why we refrain from
12 raising change control form?"
13 Do you see that?
14 A. Yeah.
15 Q. Do you know what he's
16 talking about there?
17 A. I don't.
18 Q. Do you know what a clearance
19 is?
20 A. I mean, we know clearance is
21 authorization just in general. But I
22 don't know what he's talking about here.
23 Q. I think you might have
24 obliquely referenced that there are

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1 procedures to follow on change.
2 Is that the SOP on change
3 management process -- or processes?
4 A. I don't know what it's
5 titled in MLL. But yeah, it could say
6 change management or change control.
7 MR. DAVIS: Okay. I'm
8 marking Tab 14 as Exhibit 14.
9 MR. TRISCHLER: Do you want
10 this back?
11 THE WITNESS: Okay.
12 (Document marked for
13 identification as Exhibit
14 PL-Glover-14.)
15 BY MR. DAVIS:
16 Q. Take a moment to review that
17 and let me know when you're ready to
18 discuss.
19 MR. DAVIS: Clem, I'm going
20 to go off camera and refill my
21 water glass. I'll be right back.
22 MR. TRISCHLER: Okay.
23 BY MR. DAVIS:
24 Q. Have you sufficiently

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1 reviewed the document, Mr. Glover?
2 A. I'm going to need a couple
3 more minutes. It's 41 pages.
4 Okay.
5 Q. Did you review any SOPs on
6 change management in prepping for this
7 deposition?
8 A. I don't believe so.
9 Q. Okay. Is this an SOP you've
10 reviewed before?
11 A. I have not read this one,
12 but I have reviewed the global policy.
13 Q. This SOP does fall under
14 quality assurance, correct?
15 A. Yes.
16 Q. And like the risk management
17 one that we reviewed earlier, this one
18 appears to apply to Mylan Laboratories
19 Limited and all the API manufacturing
20 sites?
21 A. Yeah.
22 Q. Including Unit 8?
23 A. Yeah.
24 Q. If you look at the

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1 "Responsibility" section, 3.1.1 says
2 that, "The originating department is
3 responsible for initiating the change
4 control in Trackwise with required
5 information."
6 Do you see that?
7 A. Yep.
8 Q. What is Trackwise?
9 A. It's an electronic system
10 used to document change control.
11 Q. And those change controls
12 are stored in that system?
13 A. They are.
14 Q. So if you were to, for
15 example, search for -- could you search
16 Trackwise?
17 A. Yeah.
18 Q. Okay. So if there were
19 change controls for substituting
20 recovered solvents for fresh solvents for
21 valsartan, would that -- would those
22 change controls live in Trackwise?
23 A. I can't say for certain when
24 Trackwise was implemented at Unit 8 or

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1 the API sites. But yes, when Trackwise
2 was implemented, from that point forward
3 that's where they would have put change
4 control.
5 I'm just -- we're talking
6 all the way back to 2012. I don't know
7 for certain when Trackwise was deployed
8 there.
9 Q. Sure. And this is from
10 December of 2015.
11 Do you see that?
12 A. I do.
13 Q. So it at least existed back
14 to then, correct?
15 A. Correct.
16 Q. Okay. Who would you -- if
17 you were, for example, in the course of
18 your responsibilities as head of global
19 quality, if you wanted to see what change
20 controls were made regarding recovered
21 solvents in valsartan throughout the
22 years, who would you go talk to about
23 that?
24 A. I would likely ask

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1 Dr. Gomes, honestly, to start with him.
2 Q. If you go to Page 4, you'll
3 see some definitions.
4 A. Okay.
5 Q. You'll see one that is a CC
6 risk assessment, do you see that, 5.4?
7 A. Yes.
8 Q. And it says that that's
9 defined as an assessment of the changes
10 which relates risk to patient safety,
11 regulatory implications, and business,
12 correct?
13 A. Yeah.
14 Q. Do you know if the -- if the
15 change from fresh to recovered solvents
16 for valsartan yielded a change control CC
17 risk assessment?
18 MR. TRISCHLER: Objection to
19 form.
20 THE WITNESS: I don't know
21 the answer to that. I think,
22 based on what we've already read,
23 it sounds like recovered solvents
24 may have been contemplated in

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1 2012. If that's the case, that
2 would be prior to approval. And
3 so it's uncertain to me whether it
4 would have required a change
5 control specific to valsartan.
6 BY MR. DAVIS:
7 Q. What do you mean by that?
8 A. I mean, if you submitted in
9 your DMF and in your applications with
10 the designation of recovered solvents,
11 then there would be no requirement for a
12 change control, because that's your
13 original submission. Normally the change
14 control process starts at square one, and
15 square one being the approval of the
16 product itself.
17 Q. Gotcha. Okay. So
18 basically, changes are evaluated based
19 on, you know, if day zero is, you know,
20 approval, anything that's changed beyond
21 approval could potentially implicate a
22 change form, but not stuff that was
23 implemented prior to approval?
24 A. Yeah. Again, it's not

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1 exclusive. I mean, they can use this
2 workflow prior to approval, if it's
3 convenient for them. But it's not always
4 mandated.
5 So -- and it certainly
6 wouldn't be all that relevant, because
7 while you're developing and submitting
8 and engaging with the health authority,
9 you have a lot of back and forth, and
10 you're making a lot of adjustments. So
11 it's not quite as rigid as it is after
12 approval.
13 Q. What about changes that are
14 made preapproval? You know, if, you
15 know, Mylan intended, for example, to
16 use -- let's stick with recovered
17 solvents, because that's what we are
18 talking about.
19 If, for example, Mylan
20 intended to use fresh solvents and then
21 prior to approval decided to use
22 recovered solvents, how would those
23 changes be archived or documented?
24 A. Are you talking about after

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1 submission?
2 Q. After submission but prior
3 to approval.
4 A. Yeah, it would --
5 MR. TRISCHLER: Objection to
6 form. Objection to form.
7 But go ahead.
8 THE WITNESS: After
9 submission, prior to approval, any
10 change would be communicated with
11 the health authority. And they
12 may use this process, but they
13 would have a process on top of
14 that that would require some type
15 of communication with a health
16 authority.
17 BY MR. DAVIS:
18 Q. What would be the process on
19 top of this one?
20 A. I think typically the
21 term -- and again, this goes a little
22 outside of my scope, but they use the
23 term "gratuitous amendment" in the United
24 States.

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1 And so regulatorily those
2 are the types of changes that would
3 typically qualify as a gratuitous
4 amendment.
5 Q. Okay. Does -- is there an
6 SOP --
7 (Zoom audio interruption.)
8 BY MR. DAVIS:
9 Q. -- on gratuitous amendments?
10 A. I don't know if there's an
11 SOP on the topic or not. That would be a
12 regulatory question.
13 Q. What about presubmission
14 changes? Are those archived in any way
15 or is that just, you know, something that
16 eventually if the change was made, it's
17 in the submission?
18 A. Yeah. It would be a
19 question for R&D. I'm not certain.
20 Q. Go to 5.16, which is
21 "Regulatory Impact."
22 A. 5.16? Oh, 5.16. Okay. Got
23 it.
24 Q. I guess before we move to

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1 that, one more question came to mind,
2 which is, for changes that are
3 postsubmission, preapproval, are those
4 changes in any way conveyed to any API
5 customers that Mylan has?
6 A. Okay. So you're talking
7 about in the API space?
8 Q. Sure. Yeah, so in the API
9 space where Mylan manufactures API and
10 supplies it to a finished dose
11 manufacturer, for changes that are
12 postsubmission, preapproval, does Mylan
13 have any procedure to notify finished
14 dose customers that it may have at that
15 point of any changes?
16 A. I don't know about
17 requirements. I know that everything is
18 transparent with the health authority, in
19 this case, in the U.S., FDA. So the DMF
20 for the API is with the FDA.
21 The customer will file his
22 finished product. And that triggers the
23 review of both the DMF and the
24 application.

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1 So at that time, you know,
2 all -- all information is there readily
3 available for FDA.
4 I can't say for certain if
5 there's a program for communication back
6 to customers if changes are implemented
7 or contemplated.
8 Q. Would that be true even
9 after approval?
10 A. I mean, I'm not sure. I
11 would be guessing as to the answer of
12 that.
13 Q. But everything should be in
14 the DMF, I guess, is what you're saying?
15 A. Yes.
16 Q. Okay. Going back to the
17 regulatory impact, 5.16 in Exhibit 14.
18 That's defined as, "Any change that
19 impacts or is associated with revisions
20 to the conditions established," and
21 there's an API section below that that
22 says, that this includes changes to
23 processes -- or I'm going to read the --
24 what I think is the relevant language and

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1 skip a little bit.
2 But, "This includes changes
3 to processes, which include but are not
4 limited to, manufacturing procedures,
5 specifications, analytical test methods,
6 raw materials," et cetera, et cetera.
7 Do you see that?
8 A. I do.
9 Q. Does the use of recovered
10 solvents or the change from fresh solvent
11 to recovered solvent, does that amount to
12 a change to a process including a
13 manufacturing procedure or raw material?
14 MR. TRISCHLER: Objection to
15 form of the question, to the
16 extent that it mischaracterizes
17 facts.
18 MR. DAVIS: Let me -- let me
19 rephrase it.
20 BY MR. DAVIS:
21 Q. Does this 5.16.3 in your
22 mind, does that -- do -- do changes from
23 fresh to recovered solvents fall within
24 the scope of this language?

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1 A. I can't say it definitively
2 does, no.
3 Q. Why not?
4 A. It would all depend on how
5 the batch manufacturing record details
6 processes.
7 In many cases, at that level
8 of solvent, it may just state "use
9 solvent" by name. It may not articulate
10 whether or not it's recovered or fresh or
11 specify either. It wouldn't be that
12 detailed.
13 In the case of valsartan, I
14 understand it did. But I can't say
15 always that would be required.
16 Q. What would be a situation
17 where it would not be required?
18 A. Again, just speculating. I
19 don't know. It would have to be a
20 case-by-case discussion with FDA.
21 And I think FDA typically
22 wants to know that you are using a
23 particular material and testing it
24 according to a particular test at against

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1 a particular spec, and that's usually
2 where the conversation ends.
3 Q. So the onus is on Mylan in
4 the first instance to notify the FDA and
5 then have that conversation with them,
6 correct?
7 A. Notify them about what?
8 Q. About the, for example, the
9 change from fresh to recovered solvents.
10 A. I don't know that we're
11 obligated to tell them about a change
12 from fresh to recovered.
13 We're obligated to comply
14 with the registration.
15 Q. Okay. Well, you said that
16 that would be whether -- you know,
17 whether there would be a regulatory
18 impact depended on those discussions.
19 So doesn't that presuppose
20 that you're informing them of it?
21 Because how can you have a discussion
22 with them otherwise, right?
23 MR. TRISCHLER: Objection to
24 form.

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1 THE WITNESS: I think --
2 yeah, purely coincidental though.
3 I mean, what detail is in the
4 batch record is -- it's just a
5 matter of who wrote the batch
6 record.
7 BY MR. DAVIS:
8 Q. When you say the batch
9 record, are you referring to the master
10 batch records for the validation batches?
11 A. For the DMF. The DMF filing
12 itself is the information that FDA has
13 and reviews.
14 Q. And there are batch records
15 that are part of that DMF?
16 A. Yeah.
17 Q. And what are those batch
18 records of?
19 A. The process, the synthetic
20 pathway.
21 Q. Are those typically called
22 validation batches?
23 A. No. I'm not used to hearing
24 that term applied to the DMF contents. I

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1 mean, you may hear that term "validation"
2 applied loosely to finished product. And
3 finished product, the submission or
4 exhibit batch can sometimes be called
5 validation batches. But --
6 Q. Is that what you're
7 referring to -- I'm sorry.
8 A. -- validation batch is a
9 much more general term.
10 Q. Yeah, I guess I'm just
11 trying to understand what is the batch
12 that you're referring to in the DMF. Is
13 that like a test batch or a submission
14 batch or what you just called it?
15 A. It's not any batch. It's
16 just a recipe, basically, for the batch
17 to put it in laypeople's terms.
18 Q. Okay. Does Mylan typically
19 run through the recipe a few times
20 before -- before commercializing?
21 MR. TRISCHLER: Objection to
22 the form. Objection beyond the
23 scope.
24 THE WITNESS: That is beyond

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1 my expertise. I can't tell you
2 precisely what the API units do
3 before they file DMF.
4 BY MR. DAVIS:
5 Q. Okay. So you wouldn't know
6 if those were called validation batches?
7 A. I would not.
8 Q. All right. Going to the
9 next page, which is Page 8 of 41. You'll
10 see some 5.22, 23, and 24 distinguished
11 between minor, major, and critical
12 changes.
13 A. Yeah.
14 Q. Do you see that?
15 A. Yeah.
16 Q. Would you agree that, at
17 least the way this is defined here, that
18 the touchstone for whether something is a
19 minor, major, or critical change is
20 patient safety?
21 A. It is one consideration. I
22 wouldn't say it's the only consideration.
23 Q. The other considerations
24 would be quality, purity, at least

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1 according to this?
2 A. Yeah. Quality for sure.
3 And quality, being defined by the ability
4 of a process to meet all regulatory
5 requirements. And a lot of those have
6 very little to do with patient safety.
7 Q. But safety is listed right
8 afterwards, correct?
9 A. Yeah.
10 Q. Okay. So anything that
11 affects -- that may have an impact on the
12 final product quality, purity or safety,
13 would be a major change, for example,
14 according to 5.23?
15 A. Yes.
16 Q. In retrospect, do you agree
17 that the change from fresh to recovered
18 solvents in valsartan had an effect on
19 product quality, purity, and safety?
20 MR. TRISCHLER: Objection to
21 the form. Misstates facts and
22 mischaracterizes evidence.
23 You can answer if you can.
24 THE WITNESS: Yeah, I -- I

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1 don't even know that this
2 implementation of recovered
3 solvents is a change control
4 discussion.
5 If it was -- if it was
6 implemented as part of the
7 original DMF, then I don't know
8 that it would be even subject to
9 change control.
10 BY MR. DAVIS:
11 Q. Let's assume that it was.
12 Would you agree that the change from --
13 and assuming that it's a change. Would
14 you agree that the change from fresh to
15 recovered solvents in valsartan had an
16 impact on the final product quality,
17 purity, or safety?
18 MR. TRISCHLER: Objection.
19 Objection to the form.
20 THE WITNESS: Sorry, can you
21 repeat it again?
22 BY MR. DAVIS:
23 Q. Sure. Assuming that the
24 change from -- assuming that moving from

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1 fresh solvents to recovered solvents was
2 indeed a change, would you agree that
3 that change had an impact on final
4 product quality, purity, or safety?
5 MR. TRISCHLER: Objection to
6 form.
7 THE WITNESS: I understand.
8 My answer is no. And based on the
9 criteria given within this SOP,
10 the change from fresh to recovered
11 solvent resulted in product that
12 met all regulatory requirements.
13 BY MR. DAVIS:
14 Q. You -- Mylan recalled it
15 though, correct?
16 A. We did.
17 Q. Because the FDA told Mylan
18 to recall it?
19 A. Because the FDA established
20 new limits to a new impurity that was not
21 previously contemplated.
22 Q. What about purity or safety?
23 Does the -- does contamination with
24 nitrosamines affect purity or safety in

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1 Mylan's opinion?
2 MR. TRISCHLER: Objection to
3 the extent that it's beyond the
4 scope of the designation.
5 Objection to form. You can answer
6 if you can.
7 THE WITNESS: Regarding
8 safety, my understanding is that
9 we've already conducted a risk
10 assessment and determined that the
11 impact to patient safety was
12 negligible.
13 Regarding purity of the
14 product, met all registered
15 specifications and limits for
16 purity.
17 BY MR. DAVIS:
18 Q. You are not designated on
19 those topics, though, are you?
20 A. I don't even know what I am
21 designated for. And I'm not -- I don't
22 know if it's listed in that list or not.
23 I'm sorry. I'm not sure.
24 Q. Because I'm happy to take

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1 that up with someone else. But you --
2 MR. TRISCHLER: He's not
3 been designated -- he's not been
4 designated -- just to make the
5 record clear, John, he's not been
6 designated on Mylan's risk
7 assessment with respect to
8 nitrosamines.
9 THE WITNESS: Human
10 toxicology, yeah, I'm not
11 designated for that.
12 MR. DAVIS: Or root cause.
13 That's fine.
14 BY MR. DAVIS:
15 Q. Would you agree that
16 changing a facility -- you know, adding a
17 facility -- a contract manufacturing
18 facility, to do solvent recovery could
19 have an impact on product quality,
20 purity, or safety?
21 MR. TRISCHLER: Objection to
22 the form.
23 THE WITNESS: Again, I need
24 you to repeat the question. I'm

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1 sorry.
2 BY MR. DAVIS:
3 Q. Would you agree that
4 adding -- let's take recovered solvents,
5 for example, again, and twist the
6 hypothetical around a little bit.
7 Let's say that Mylan was
8 recovering solvents at Unit 8 for
9 valsartan and then decided to outsource
10 those recovery operations to a contract
11 manufacturing unit, or a CMU. Would that
12 change potentially have an impact on
13 final product quality, purity, or safety
14 in your opinion?
15 MR. TRISCHLER: Objection to
16 form.
17 THE WITNESS: Any -- any
18 change contemplated in the GMP
19 process has potential to impact,
20 and that's why we do the
21 evaluation.
22 BY MR. DAVIS:
23 Q. That's why you do a change
24 control risk assessment, is what you're

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1 saying?
2 A. Correct.
3 MR. TRISCHLER: Hey, John,
4 it's 12:15. I'd like to take a
5 lunch break.
6 MR. DAVIS: Sure.
7 MR. TRISCHLER: At least
8 it's 12:15 here. I'm not sure --
9 it's probably 11:15 at your place,
10 but let's take a lunch break, if
11 we can.
12 MR. DAVIS: Let me see if I
13 have any more cleanup on this.
14 Yeah, this is a good time.
15 What time do you want to come back
16 on?
17 MR. TRISCHLER: I think we
18 can shoot for 1 o'clock on this
19 end.
20 MR. DAVIS: Sure. That's
21 fine.
22 MR. TRISCHLER: If that's
23 fine for you and everybody else.
24 MR. DAVIS: Yeah, actually

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1 let's give it a full hour --
2 MR. TRISCHLER: Is that okay
3 with everybody else?
4 MR. DAVIS: Let's give it a
5 full hour and do 1:15 your time.
6 MR. TRISCHLER: Okay.
7 THE VIDEOGRAPHER: The time
8 right now is 12:15 p.m., and we
9 are off the record.
10 - - -
11 (Whereupon, a luncheon
12 recess was taken.)
13 - - -
14 AFTERNOON SESSION
15 - - -
16 THE VIDEOGRAPHER: The time
17 right now is 1:20 p.m., and we're
18 back on the record.
19 - - -
20 EXAMINATION (Cont'd.)
21 - - -
22 BY MR. DAVIS:
23 Q. All right. Mr. Glover, did
24 you review any documents on the break?

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1 A. I did not.
2 MR. DAVIS: I'm going to
3 introduce what I've marked as Tab
4 101 as plaintiffs Exhibit 15.
5 (Document marked for
6 identification as Exhibit
7 PL-Glover-15.)
8 MR. DAVIS: And then what
9 I'm going to do is share my
10 screen.
11 BY MR. DAVIS:
12 Q. Okay. Can you see that,
13 Mr. Glover?
14 A. Yes.
15 Q. Let me represent to you that
16 I pulled this document off the FDA's
17 website.
18 And for the record the URL
19 is HTTPS --
20 MR. DAVIS: I'm getting some
21 feedback.
22 Also, Brad, can you turn
23 your camera back on from our
24 earlier discussion? You can keep

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1 yourself muted, but please turn
2 your camera back on, if you're in
3 the room. Thank you.
4 For the record, the URL on
5 this, Exhibit 15, it's
6 <https://www.fda.gov/media/92818/>
7 download.
8 And it's a 57-page PDF
9 document of what looks to be a
10 July 15-16, 2015 presentation
11 given by a gentleman named Robert
12 Iser.
13 Do you know who Robert Iser
14 is, Mr. Glover?
15 THE WITNESS: I'm familiar
16 with his name.
17 BY MR. DAVIS:
18 Q. He's an FDA employee?
19 A. That's my understanding.
20 Q. Have you seen this
21 presentation --
22 A. Was -- was an FDA.
23 Q. Was. Okay. We talked
24 earlier a little bit about quality and

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1 I'm going to paraphrase what I think you
2 said, and feel free to correct me if I'm
3 wrong.
4 But you said that your
5 definition of quality was simply meeting
6 the predefined spec. Do you remember
7 that?
8 A. I don't remember saying that
9 the way you said it. But I remember
10 establishing -- I think we had a
11 conversation about the failure of quality
12 or something to that effect.
13 Q. And how did you define it?
14 A. In the context of the
15 document we were reading, I was
16 interpreting that paragraph to mean a
17 failure to meet the established
18 acceptance criteria.
19 Q. That would be Exhibit 7, I
20 believe, which is the first iteration of
21 the unsigned draft risk assessment we
22 looked at?
23 A. Correct.
24 Q. Okay. But you didn't write

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1 that, did you?
2 A. No.
3 Q. And you never looked at it
4 before today?
5 A. No.
6 Q. Do you personally know any
7 of the people that wrote that?
8 A. I need to look at it again
9 to see the names, but I don't believe so.
10 Would you like me to go find it?
11 Q. Sure. Why don't you -- why
12 don't you take a look at it. It's Tab --
13 Exhibit 6 and 7.
14 We can skip this exercise if
15 you're just willing to agree that you're
16 speculating as to what they meant by it,
17 correct? You don't have personal
18 knowledge of how that word was used
19 there, do you?
20 A. I can interpret it in
21 context, no different than anyone else.
22 I don't think I know any of these people,
23 no.
24 Q. In what context -- you said

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1 that you can interpret it based on the
2 context, what context makes you think
3 that quality failure there simply means
4 failure to meet the predefined spec?
5 A. Hang on. Let me go back to
6 the document and I'll --
7 Just my experience of
8 hearing folks use language like this.
9 When we say "lead to quality failure of
10 the product," there's two predominate
11 ways people would make that statement.
12 Either it's -- failure of
13 the product would be rejection of the
14 product, or failure of the product would
15 be failure of the product to meet the
16 established acceptance criteria.
17 I'm not used to hearing
18 folks in quality use that language in any
19 other way. That's the context that I
20 would provide.
21 Q. Well, it's referencing the
22 API right next to it, is it not, under
23 description of risk?
24 A. Sure. And whether it was

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1 API or finished product, that statement
2 still, to me, means the same thing.
3 Q. And below that it references
4 contamination as impurities under the
5 description of the risk, correct?
6 A. In a different section?
7 Q. No. In the same section,
8 just the different -- the column that
9 identifies the description of the risk
10 and then there's --
11 A. Yeah. And, again, the
12 inference would be that the contamination
13 would manifest in a product that doesn't
14 mean the registered acceptance criteria.
15 Q. So how are you defining --
16 again, what context makes you think that
17 quality failure is simply failure to meet
18 the spec when it's discussing this in the
19 context of contamination and impurities
20 in the API?
21 MR. TRISCHLER: Objection.
22 Asked and answered.
23 THE WITNESS: Yeah, again, I
24 believe that my experience of

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1 interpreting language such as this
2 is that we would rely on the
3 registered established acceptance
4 criteria for quality failure type
5 of language.
6 BY MR. DAVIS:
7 Q. You don't have anything
8 other than your experience that you're
9 relying on there, do you?
10 A. That is my experience. And
11 I've worked in this field a long time,
12 so...
13 Q. So how are you defining
14 quality there then?
15 A. Quality failure is what you
16 would need to define. I don't think you
17 define quality. Quality failure in the
18 sentence I define as a failure of the
19 product to meet the established
20 acceptance criteria.
21 Q. It says quality though,
22 right? I mean, a failure is the failure
23 of quality. So talk to me about what you
24 interpret quality to mean.

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1 MR. TRISCHLER: Objection.
2 Excuse me. Objection to form.
3 THE WITNESS: Again, I
4 interpret quality failure as a
5 failure of the product to meet the
6 established acceptance criteria.
7 BY MR. DAVIS:
8 Q. Okay. But again, you didn't
9 write this and you don't know the people
10 who wrote it, and you never saw it before
11 today?
12 A. That's correct.
13 Q. Okay. I'm going back to
14 exhibit -- what I believe is 15, which is
15 what I've pulled off the FDA website and
16 is a presentation by Robert Iser, who you
17 testified was formerly an FDA employee.
18 He was an FDA employee at
19 the time that he gave this presentation?
20 Do you know?
21 A. I think so. I'm not sure if
22 he's still there or not. But in 2015, I
23 believe he was.
24 Q. Take a look at Page 3, which

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1 is -- I'm screen sharing it for you. It
2 says, "Stop. First things first, what is
3 quality?"
4 Do you see that?
5 A. Yep.
6 Q. And then the next page with
7 the header, "What is quality of a
8 pharmaceutical product?"
9 Can you read those -- aloud
10 those bullet points in quotation?
11 A. "It delivers the properties
12 described on the label and is not
13 contaminated - Dr. Woodcock.
14 "Fitness for intended use.
15 "Freedom for defects.
16 "Meeting or exceeding
17 customer expectations.
18 "Customer's definition of
19 quality is the only one that matters.
20 "Modified from Juran and
21 Deming."
22 Q. Who is Dr. Woodcock?
23 A. At the time she was the head
24 of CDER, I believe.

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1 Q. Okay. What is CDER? What
2 is that acronym?
3 A. Center for Drug, something,
4 Research. It's one of the FDA
5 subdivisions.
6 Q. Is there anything about
7 these definitions of quality that Mylan
8 disagrees with?
9 A. I don't know that I agree or
10 disagree with the statements. I think
11 that they are vague and not further
12 defined. And so without the definition
13 of the word "contaminated," it's just a
14 general statement from Dr. Woodcock.
15 Q. What's there to be confused
16 about with the definition of
17 "contaminated"?
18 A. There's plenty to be
19 interpreted about the word
20 "contaminated." And so if inferences are
21 made that contaminated means that
22 impurities are present, then all drugs
23 have impurities. And it makes no sense
24 to make a blanket statement that no drug

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1 should have impurities.
2 Q. So there's nothing that you
3 disagree with about this statement, is
4 there?
5 MR. TRISCHLER: Objection to
6 form.
7 BY MR. DAVIS:
8 Q. Or these bulleted statements
9 on Page 4 of this Exhibit 15?
10 MR. TRISCHLER: Objection to
11 form. You've repeated the
12 question. He's asked and answered
13 it. It's asked and answered.
14 BY MR. DAVIS:
15 Q. You can answer again.
16 A. Again, I don't disagree with
17 any statements made, but emphatically
18 feel they are generalized and could be
19 taken out of context.
20 I don't believe that
21 inferences between contamination and
22 presence of impurities is appropriate.
23 Q. But you acknowledge that the
24 FDA -- that FDA employees wrote this and

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1 are quoting other FDA employees saying
2 this, correct?
3 MR. TRISCHLER: Objection to
4 form.
5 THE WITNESS: I understand
6 that former and current FDA
7 employees were involved in this
8 presentation.
9 BY MR. DAVIS:
10 Q. You mentioned Dr. Gomes. He
11 reports directly to you, correct?
12 A. Yes.
13 Q. Would Dr. Gomes have been
14 directly involved in the process
15 validation work regarding API processes
16 for Mylan's drug products?
17 A. In what time frame?
18 Q. Any time from, you know,
19 initial development of valsartan through
20 present.
21 A. I mean, he is currently the
22 head of API quality and has been for at
23 least two or three years.
24 What his involvement is on

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1 the front-end development, I'm not
2 certain.
3 Q. Does process validation fall
4 within API quality if it relates to API?
5 A. In some regard, yes. It
6 depends, again, on how you use the word
7 process validation.
8 Q. How do you use the word
9 process validation?
10 A. My definition of process
11 validation includes all three phases of
12 development, qualification, and continued
13 process monitoring.
14 Q. So three phases meaning
15 chronological phases, and you said -- can
16 you go through that again for me?
17 There's three phases. What's the first
18 one?
19 A. Development.
20 Q. And what is development?
21 Let's just stick with development for a
22 second.
23 When does the development
24 phase end?

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1 A. It ends at the time of
2 approval and then you go into
3 qualification of the process --
4 Q. And then --
5 A. -- to be more specific.
6 There are occasions where
7 you might actually start qualification
8 when you're anticipating approval. It's
9 not a very good idea to do it very early,
10 because you may get changes coming out of
11 your health authority review.
12 So it typically coincides
13 closely with the approval process.
14 Q. What is the qualification --
15 what work is involved in the
16 qualification process typically?
17 A. It varies broadly. Sorry.
18 MR. TRISCHLER: Objection to
19 form.
20 THE WITNESS: And it would
21 depend on the case.
22 MS. HILTON: John, you're
23 just sharing your screen. Just as
24 an FYI, you're still sharing.

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1 MR. DAVIS: Yeah. Let's
2 take that down.
3 BY MR. DAVIS:
4 Q. I'm going to introduce --
5 well, actually, do you -- are you
6 familiar with a World Health Organization
7 inspection of Mylan Unit 3 that occurred
8 in June 2014?
9 A. I don't have it committed to
10 memory. I'm sure I probably saw the
11 report at some point in my travels.
12 Q. Okay. Did Unit 3 make
13 valsartan API?
14 A. My understanding is that
15 they were an early manufacturing site for
16 the API.
17 MR. DAVIS: I'm marking Tab
18 16 as Exhibit 16.
19 (Document marked for
20 identification as Exhibit
21 PL-Glover-16.)
22 MR. DAVIS: And Tab 17 as
23 Exhibit 17.
24 (Document marked for

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1 identification as Exhibit
2 PL-Glover-17.)
3 THE WITNESS: Okay. I have
4 both documents.
5 BY MR. DAVIS:
6 Q. Exhibit 16 is just an
7 e-mail. It attaches the -- a document
8 called Mylan CAPAs_Comments From
9 Inspectors.docx.
10 Do you see that?
11 A. Yes.
12 Q. And Dr. Gomes is one of the
13 recipients of this e-mail, is he not?
14 A. Yes.
15 Q. Okay. Then turn to
16 Exhibit 17. You'll see that the title of
17 the document is WHO Audit Compliance
18 Report.
19 Do you see that?
20 A. Yep.
21 Q. And that it relates to API
22 Unit 3, that the contact person is
23 Dr. Gomes, and that the date of
24 inspection is June 16th to 19, 2014?

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1 A. Yep.
2 Q. Okay. Does this look like
3 to you it's Mylan's responses to the
4 WHO's observations from that inspection?
5 A. I mean, it looks like it
6 could be at least a draft response or
7 update. I can't quite tell which.
8 Q. Sure.
9 A. Actually, it's got
10 assessment by inspector language in it
11 also. That's a little confusing for me.
12 I'm not used to seeing that in a
13 response.
14 Q. Let's go through those
15 columns. Observations would be the WHO
16 inspector's observations, correct?
17 A. Yeah.
18 MR. TRISCHLER: Objection to
19 form.
20 BY MR. DAVIS:
21 Q. Proposed CAPA, does that
22 strike you as Mylan's responses?
23 A. Typically that's where we
24 would put our proposal, yes.

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1 Q. Okay. And then assessment
2 by inspector might be the inspector's
3 responses to those proposed CAPAs?
4 A. It's possible. But I'm not
5 used to seeing that. So that would infer
6 that this came from WHO instead of from
7 us. But the e-mail seems to come from
8 our employee.
9 And it says forwarding the
10 report for preparation, as if it's
11 something that our guys are working on.
12 So I'm not exactly sure what
13 assessment by inspector means.
14 Q. I assume you might want to
15 refer me to Dr. Gomes, since he is the
16 contact person on this?
17 A. I think it's a very good
18 idea that he would probably know what was
19 going on with that last column.
20 MR. TRISCHLER: Excuse me.
21 Mr. Glover, try to wait until
22 Mr. Davis finishes his question
23 because I think what will happen
24 is that the two of you will drown

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1 each other out, and the court
2 reporter won't be able to hear
3 anything due to the mechanics of
4 trying to do this remotely, okay?
5 THE WITNESS: Apologies.
6 BY MR. DAVIS:
7 Q. I'll try not to stomp over
8 you either.
9 So on Page 4 of the
10 document, you'll see -- and we're under
11 major observations.
12 Do you see that at the top
13 of these pages, including Page 4?
14 A. Yes.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

1 Q. Are those done annually?

2 A. Typically, yes.

3 Q. And what would -- what
4 information would go into them?

5 A. Again, it widely varies.

6 It's intended to be a yearly review of
7 various key aspects of product
8 performance.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

22 MR. DAVIS: Okay. I'm going
23 to mark Tab 18 as Exhibit 18.
24 (Document marked for

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[REDACTED]

1 identification as Exhibit
2 PL-Glover-18.)
3 BY MR. DAVIS:
4 Q. Do you recognize this as
5 another one of these FDA guidance
6 documents?
7 A. Yep.
8 Q. And this one relates to
9 process validation?
10 A. Yep.
11 Q. Dated January 2011?
12 A. Yeah.
13 Q. Have you looked at this
14 document before?
15 A. Yes, years ago.
16 Q. Take a look at the page that
17 has the Number 4 at the bottom of it.
18 We'll go by the numbering at the bottom
19 of these pages.
20 A. Okay.
21 Q. Do you see where it says,
22 "For purposes of this guidance, process
23 validation is defined as the collection
24 and evaluation of data from the process

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1 design stage through commercial
2 production which establishes scientific
3 evidence that a process is capable of
4 consistently delivering quality product?"
5 A. Yeah.
6 Q. Does Mylan take any issue
7 with that definition of process
8 validation?
9 A. No.
10 Q. Can you describe to me why
11 process validation is important?
12 A. In general, process
13 validation, we rely on it to establish
14 consistency from batch to batch,
15 reliability of the process.
16 Q. And other things such as
17 safety and identity, purity?
18 A. We tend to rely --
19 MR. TRISCHLER: Objection to
20 form.
21 THE WITNESS: We tend to
22 rely on the registered acceptance
23 criteria more for that.
24

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1 BY MR. DAVIS:
2 Q. Well, it says in the same
3 page, just below, in the middle
4 paragraph, that, "The manufacturer should
5 have gained a high degree of assurance in
6 the performance of the manufacturing
7 process such that it will consistently
8 produce APIs and drug products meeting
9 those attributes relating to identity,
10 strength, quality, purity, and potency."
11 Do you see that?
12 A. Yes. And those attributes
13 are reflected in the acceptance criteria
14 for the product.
15 Q. What do you mean by
16 acceptance criteria for the product?
17 A. The registered
18 specifications, test methods,
19 manufacturing conditions.
20 Q. Doesn't this go back to our
21 dispute about what the definition of
22 quality means? You keep trying to limit
23 it to the specification, but that's
24 clearly not what the FDA is saying,

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1 right?
2 MR. TRISCHLER: Objection
3 to -- objection to form.
4 THE WITNESS: So far, I
5 think that's exactly what FDA is
6 saying. I mean, the way I read
7 these sentences is that FDA is
8 reflecting back to attributes.
9 And if you hear them talk
10 about quality attributes, quality
11 attributes are measurable,
12 measurable and determined to be
13 reflected against the established
14 acceptance criteria in the
15 registration.
16 BY MR. DAVIS:
17 Q. I don't see that in that
18 sentence that I just read.
19 MR. TRISCHLER: Is that a
20 question or just a declarative
21 statement? Because if it's a
22 question, objection to form. I
23 mean, you're arguing.
24 BY MR. DAVIS:

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1 Q. Do you see that statement in
2 that paragraph that we're looking at?
3 MR. TRISCHLER: Objection to
4 form.
5 BY MR. DAVIS:
6 Q. -- that you just said --
7 where do you see the word "acceptance
8 criteria" on that paragraph -- in that
9 paragraph?
10 A. I'm simply stating that the
11 term attributes in quality GMP language
12 is typically preceded by the words
13 critical quality attributes or CQA. It's
14 a commonly used term in our business.
15 When FDA references attributes such as
16 identity, strength, quality, purity, and
17 potency, these are all quality attributes
18 that are measured and tested.
19 And those measurements and
20 testing are performed in accordance with
21 the registered specifications and
22 acceptance criteria established in the
23 application.
24 Q. That's not one of the

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1 definitions that we read in Exhibit 15,
2 that the FDA provided in its
3 presentation, is it, though, for quality?
4 A. Mr. Iser's presentation may
5 or may not have been comprehensive in all
6 GMP terminology. I can't speak to what
7 his intention was.
8 Q. Move to the next page if you
9 don't mind, page Number 5.
10 And it says, just below
11 Header 3, "Process validation for drugs,
12 finished pharmaceuticals, and components
13 is a legally enforceable requirement."
14 Do you see that?
15 A. Yep.
16 Q. Does Mylan agree that
17 process validation is a legally
18 enforceable requirement under 21 U.S.C.
19 351(a)(2)(b)?
20 MR. TRISCHLER: Objection to
21 form and foundation.
22 THE WITNESS: I'm not a
23 lawyer. I couldn't possibly weigh
24 in on whether this statement is,

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1 you know, something that we agree
2 with or disagree with.
3 I know that the premise of
4 the guidance is that it's FDA's
5 current thinking or suggested best
6 practices.
7 So I don't -- I can't weigh
8 in on a statement like this. It's
9 outside the scope of my expertise.
10 BY MR. DAVIS:
11 Q. Do you agree that at
12 minimum, the FDA views process validation
13 as really important?
14 A. Yeah.
15 Q. Look below where it says,
16 "Process validation is required in both
17 general and specific terms by the cGMP
18 regulations in Parts 210 and '11."
19 Do you see that?
20 A. Yeah.
21 Q. Does Mylan agree that
22 process validation is required in both
23 general and specific terms by 21 C.F.R.
24 Parts 210 and '11?

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1 A. We understand process
2 validation is required. But the
3 definition of process validation and the
4 extent with which it needs to be
5 conducted is variable based on the case
6 and circumstances.
7 Q. If the FDA told Mylan that
8 it should process validate something,
9 does that mean it's required?
10 MR. TRISCHLER: Objection to
11 form.
12 THE WITNESS: I don't
13 understand the question. Could
14 you repeat it?
15 BY MR. DAVIS:
16 Q. Sure. Is the FDA the final
17 arbiter of what process validation is
18 required under Parts 210 and 11?
19 A. No. I mean, FDA obviously
20 has a heavy hand in suggesting best
21 practices. But they don't necessarily
22 get to establish new legal -- legal
23 statute without, you know, working
24 through amendments to the GMP.

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1 So there's a process by
2 which things like that can be mandated.
3 We usually don't get that far in the
4 industry because we typically agree on a
5 best practice and move forward.
6 Q. Well, it says -- I mean, the
7 FDA is saying that under the current --
8 you know, at least as of 2011 when this
9 document was written, that under the then
10 current cGMP regulations, that process
11 validation was required in specific
12 terms.
13 If the FDA told -- told
14 Mylan, for example, that process
15 validation was required for some
16 particular process, isn't the agency the
17 person best able to interpret its own
18 regulations?
19 MR. TRISCHLER: Objection.
20 Objection to the form of the
21 question.
22 THE WITNESS: I think the
23 best way to answer your question
24 is just to explain that while

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1 process validation may be expected
2 by FDA, process validation is not
3 a black-and-white,
4 one-size-fits-all type of process
5 or program.
6 It is highly variable,
7 customized per case, and nothing
8 in this document precludes that or
9 mandates a particular
10 interpretation of it.
11 BY MR. DAVIS:
12 Q. Sure. It's not expected of
13 the FDA. It's required of the FDA,
14 correct? That's what this document says,
15 right, that process validation is
16 required, right?
17 A. It's required in certain
18 cases, yes.
19 Q. And if the FDA said that a
20 certain case was one of those cases where
21 it was required, then it's required,
22 right?
23 MR. TRISCHLER: Objection to
24 the form.

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1 THE WITNESS: Yeah, I didn't
2 understand that either.
3 BY MR. DAVIS:
4 Q. Okay. If FDA --
5 A. If the FDA says it's
6 required, then it's required?
7 Q. Sure. You said in certain
8 cases it may be required, right?
9 And the FDA --
10 A. Sure. Yes.
11 Q. -- said any particular case
12 was one of those certain cases where it
13 was required, the FDA has the final word
14 on that, right?
15 A. No, I disagree. I mean, if
16 an FDA walks through the door and says,
17 "I require validation," it doesn't
18 necessarily mean that that's the law.
19 That means it's his opinion. And there's
20 a process for that as well, where you can
21 have a discussion with FDA and have a
22 debate about it. It's just not that
23 black and white.
24 Q. Okay. What about from

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1 Mylan's own internal perspective? Does
2 Mylan want to ensure that its processes
3 work in the way they intend them to?
4 A. Yep.
5 Q. Take a look at the top of
6 Page 6.
7 A. Okay.
8 Q. The FDA says, "For example,
9 Section 211.110(a), Sampling and Testing
10 of in-Process Materials and Drug
11 Products, requires the control procedures
12 be established to monitor the output and
13 to validate" -- and that's emphasized --
14 "the performance of those manufacturing
15 processes that may be responsible for
16 causing variability in the
17 characteristics of in-process material
18 and the drug product."
19 Do you see that?
20 A. Yep.
21 Q. Would recovered -- would
22 recovered solvents potentially be
23 responsible for causing variability in
24 the characteristics of in-process

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1 material of the drug product?
2 MR. TRISCHLER: Objection to
3 form. Incomplete hypothetical.
4 BY MR. DAVIS:
5 Q. Let me start somewhere else.
6 Is solvent an in-process material?
7 A. No. I don't think, by these
8 definitions.
9 I think we tend to classify
10 a solvent as a raw material for -- for
11 API manufacturing. I think that's the
12 term that I'm used to hearing.
13 In-process materials, I think, tend to be
14 intermediates in drug products in this
15 vocabulary.
16 Q. Where do you see a
17 definition of in-process material here?
18 A. You won't find it. I don't
19 see it in this paragraph either. Again,
20 I'm just leveraging my own experience of
21 those terms.
22 Normally when I hear the
23 terms "in-process materials" and
24 "intermediates," those are used somewhat

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1 interchangeably. Drug product is almost
2 always finished product. API and the
3 precursors to API are either -- or share
4 a primary or secondary intermediate are
5 also intermediate, and then solvents I've
6 always heard clustered in something
7 called raw materials.
8 But again, I'm --
9 Q. Solvents are used during the
10 manufacturing process, correct?
11 A. They are.
12 Q. And solvents -- I think this
13 is an easy one. They're materials,
14 correct?
15 A. They are.
16 Q. Do you know if Mylan did any
17 process validation work for the use of
18 recovered solvents in valsartan prior to
19 recall at any point prior to recall?
20 A. My understanding is that
21 valsartan API was originally developed,
22 submitted in the DMF validated with the
23 recovered solvent. It was always a
24 recovered solvent that was in the DMF,

Page 199

1 and the DMF reflects that.
2 So again, I haven't reviewed
3 that information. But my understanding
4 is that the answer is yes, that the
5 original development and validation
6 included recovered or used exclusively
7 recovered solvents, and that that was
8 transparently disclosed in the DMF to
9 FDA.
10 Q. Are you referring to what we
11 were talking about earlier, like the
12 validation batches?
13 A. So again, the use of the
14 word "validation batch," I'm not sure
15 whether they called it exhibit,
16 validation, or submission batches. But
17 there will be something in the DMF that
18 was provided to FDA that would have been
19 batches manufactured, set down on
20 stability.
21 And my understanding is
22 those batches were made with recovered
23 solvent, and that the DMF clearly
24 reflects that.

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1 Q. So I would refer to the DMF,
2 then, to get an answer on whether -- on
3 whether that was done?
4 A. Sure.
[REDACTED]

[REDACTED]

7 MR. TRISCHLER: Hey, John,
8 while he's reviewing that, I'm
9 going to run to the men's room if
10 that's all right.
11 MR. DAVIS: Sure. That's
12 fine.
13 MR. TRISCHLER: And even if
14 it's not all right, I'm going to
15 run to the men's room.
16 MR. DAVIS: All right.
17 Sounds good. I'll wait to ask any
18 questions.
19 MR. TRISCHLER: Okay. Thank
20 you.
21 MR. DAVIS: No problem.
22 BY MR. DAVIS:
23 Q. Mr. Glover, let me know when
24 you're ready.

Page 202

1 A. Okay. Thanks.
2 Okay.
3 Q. So if you look at page -- if
4 you see in the top right corner there's a
5 numbering convention. If you look at
6 Page 2 of 9.
7 A. Yep.
8 Q. You'll see that the purpose
9 of the audit was to approve Mylan as an
10 approved supplier of valsartan.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. Those discussions you
23 referenced, were those with counsel or
24 other Mylan individuals?

Page 203

1 A. I'm not exactly sure. I
2 think it might have been with the review
3 team.
4 Q. When you say the review
5 team, who do you mean by that?
6 A. Sorry. Jason Reefer, Brad
7 Matta. It's always possible Dr. Gomes
8 may have been in that conversation as
9 well. I'm pretty fuzzy on the details.
10 Q. Have you -- did you -- have
11 you talked to Dr. Gomes or any other
12 Mylan personnel that are not counsel
13 without the presence of lawyers in
14 preparing -- in preparing for the
15 deposition?
16 A. Not in preparing for the
17 deposition. But I speak to Dr. Gomes
18 every day. We work together.
19 Q. If you go to the
20 second-to-last page, which is numbered 8
21 of 9. And actually starting on the
22 bottom of Page 7, you'll see where audit
23 findings start. And then they spill over
24 into Page 8.

Page 204

1 A. Okay.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
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18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

13 Q. Well, did Mylan -- are you
14 aware of Mylan ever saying, "Hey, that's
15 confusing. Can you tell us what you mean
16 by that so we can respond?"
17 A. Yeah, I wasn't involved in
18 the response, so I don't know what the
19 response says.
20 Q. Who would have been involved
21 in this response?
22 A. Most likely Dr. Gomes.
23 MR. DAVIS: Okay. I'm going
24 to mark Exhibits 20 -- that's Tab

1 25 -- and Exhibit 21, which is Tab
2 26.

3 (Document marked for
4 identification as Exhibit
5 PL-Glover-20.)

6 (Document marked for
7 identification as Exhibit
8 PL-Glover-21.)

9 THE WITNESS: Okay.

10 BY MR. DAVIS:

11 Q. So let me know when you've
12 had a chance to review --

13 MR. DAVIS: What were the
14 exhibit numbers on these again,
15 Clem.

16 MR. TRISCHLER: I have 20
17 and 21.

18 MR. DAVIS: 20 and 21.

19 BY MR. DAVIS:

20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

25 [REDACTED]
26 [REDACTED]
27 [REDACTED]
28 [REDACTED]
29 [REDACTED]
30 [REDACTED]
31 [REDACTED]
32 [REDACTED]
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137 [REDACTED]
138 [REDACTED]
139 [REDACTED]
140 [REDACTED]
141 [REDACTED]
142 [REDACTED]
143 [REDACTED]
144 [REDACTED]
145 [REDACTED]
146 [REDACTED]
147 [REDACTED]
148 [REDACTED]
149 [REDACTED]
150 [REDACTED]

6 Q. Let me unscramble that a
7 bit.

8 What you're saying is how
9 you're interpreting this is that since
10 recovered solvents were validated in the
11 DMF, that validation was not extended to
12 recovered solvents after that?

13 A. Yes. So there's a bunch of
14 ways to validate things, and so you could
15 choose to validate solvent recovery all
16 by itself and stop right inside the
17 validation of the recovery itself.

18 So you can do your testing
19 of the recovered solvents and call that a
20 validation. Or you can do what these
21 guys did. They actually took the
22 recovery of solvents, incorporated it
23 into the validation process -- or
24 valsartan process validation, which would

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1 have allowed for a far more extensive
2 battery of testing at both intermediate
3 stages and at the finished API stage. It
4 would have given them a greater degree of
5 assurance that the recovered solvent was
6 going to produce valsartan API that met
7 all registered acceptance criteria, which
8 it sounds like that's what they did.

9 Q. Let me ask you, if the
10 recovered solvents were just simply
11 listed in a master batch production
12 record as an option but not actually
13 manufactured as part of the test batches
14 or validation batches or whatever you
15 want to call them, that's not process
16 validation, is it?

17 A. I'm sorry. Could you say
18 that again?

19 Q. Is simply listing something
20 in a master batch production record in
21 the recipe process validation, or do you
22 actually have to do some work on top of
23 that?

24 A. No. You would do the work.

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1 And so it sounds like these guys did the
2 work, as you said, in preparation for the
3 DMF filing. And it was all bundled in
4 the validation of the valsartan -- of the
5 API process itself.

6 Q. I don't see, though, in the
7 response where it says we did this in the
8 DMF. Where in this language in their
9 response are they saying that?

10 A. I'm making the critical
11 assumption that the valsartan process
12 validation preceded or was inclusive in
13 the DMF.

14 And in fairness, I cannot
15 say for certain. I just am presuming,
16 because DMFs require validation, that
17 this is the validation they're
18 referencing.

19 [REDACTED]

[REDACTED]

<p>1</p> <p>Page 214</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

Page 218

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 220

1 right?
2 A. As good as I could do. I'm
3 not sure.
4 Q. Do you know this person?
5 A. It sounds familiar. I
6 couldn't say for certain.
7 Q. He's e-mailing some
8 colleagues and he says, "Please prepare
9 following list for RS validation status."
10 And there's a table there, and recovered
11 solvent is one of the columns.
12 Do you see that?
13 A. Yeah.
14 Q. Do you read him as asking
15 for the status of recovered solvent
16 validation to be provided to him?
17 A. It looks like he's asking
18 for a tentative date for completion.
19 Q. If not completed, right?
20 MR. TRISCHLER: Objection to
21 form.
22 BY MR. DAVIS:
23 Q. Because there's also a
24 column for a completed date.

8 MR. DAVIS: Okay. Let's --
9 let me mark something else.
10 I'm marking Exhibit 23 which
11 is Tab 20.
12 (Document marked for
13 identification as Exhibit
14 PL-Glover-23.)
15 THE WITNESS: Okay.
16 BY MR. DAVIS:
17 Q. Do you see that this e-mail
18 is just a few days before Dr. Gomes'
19 e-mail on November 26, 2018?
20 A. Okay. Yeah.
21 Q. Okay. And then the very
22 bottom e-mail, the subject of it is
23 "Recovered Solvents." And
24 Mr. Sreenivasarao -- did I get that

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1 Do you see that?
2 A. Sure.
3 Q. And then the very top
4 e-mail, do you see that on Page 1?
5 A. I do.
6 Q. Which is an e-mail back to
7 him. It says, "Dear sir, we have not yet
8 done any recovery solvent validation at
9 Unit 8. As per new procedure, we have to
10 plan accordingly."
11 Do you see that?
12 A. Yep.
13 Q. Were you aware that Unit 8
14 was not doing any recovery solvent
15 validation?
16 A. Again, I don't know what it
17 means. It looks like it's taken at least
18 somewhat out of context.
19 And they say, "As per new
20 procedure."
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 222

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 Q. As head of global quality,
9 would you view it as problematic if there
10 was no recovery solvent validation work
11 done in the DMF and there was no recovery
12 solvent validation done at Unit 8 at any
13 point for valsartan?
14 A. Again, it would all depend
15 on our definition of our words "recovery
16 solvent validation." As long as the API
17 process is sufficiently validated, then I
18 would be comfortable, and the DMF would
19 not be approved within an application
20 unless it was found acceptable.
21 And so that infers that FDA
22 has also reviewed it.
23 Q. Assuming that Mylan had
24 disclosed everything correctly, right?

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1 A. I think if FDA would see
2 something missing, they would be the
3 first to tell us about it. We get DMF
4 deficiency letters all the time.
5 MR. DAVIS: Did I mark the
6 attachment to this e-mail?
7 MR. TRISCHLER: No.
8 MR. DAVIS: Tab 21 is
9 Exhibit 24.
10 (Document marked for
11 identification as Exhibit
12 PL-Glover-24.)
13 BY MR. DAVIS:
14 Q. Let me know when you have
15 that Excel spreadsheet up. Mr. Glover,
16 do you have a printed copy of it, or are
17 you looking at it on a computer?
18 A. I have a printed copy. It's
19 in front of me.
20 Q. Do you see that this list
21 includes all of the products manufactured
22 at Unit 8 at the time?
23 A. I can only assume that's
24 right. I don't have the products at Unit

Page 224

1 8 memorized. But it looks like a pretty
2 extensive list.
3 Q. Okay. And you'll see in
4 Rows 113 through 128, is valsartan with
5 various process codes including VST, VAA,
6 VLN, and stages.
7 Do you see that?
8 A. Yeah, I don't have the
9 numbers just so you know, but I do see
10 them.
11 Q. Okay. And the validation
12 completed date is blank.
13 Do you see that?
14 A. It looks like both of the
15 right columns are blank for everything.
16 Q. For every single one of the
17 products, right?
18 A. Right.
19 MR. DAVIS: Okay. I'm
20 marking Tab 22 as Exhibit 25.
21 (Document marked for
22 identification as Exhibit
23 PL-Glover-25.)
24 BY MR. DAVIS:

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1 Q. This e-mail is one day after
2 Dr. Gomes' e-mail. Do you see that, that
3 we looked at earlier, November 30th --
4 oh, wait, sorry, never mind. I take that
5 back.
6 November 30, 2019, do you
7 see that?
8 A. Okay.
9 Q. And do you see in the
10 first -- the bottom e-mail there's a
11 reference to CAPA details. And as we
12 mentioned CAPAs or corrective and
13 preventive actions, right?
14 A. Yeah.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

<div>Page 226</div> <div>1</div> <div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

Page 230

[REDACTED]

Page 232

1 MR. DAVIS: Sure.
2 MR. TRISCHLER: I have a
3 call at 3:30 that I've got to
4 take. So I'd like to stop at
5 3:30. And then if it runs longer
6 than 15 minutes or so, you know,
7 we'll take a 15-minute break, I
8 would propose, at 3:30.
9 If it runs long -- if my
10 call runs longer than that, a few
11 minutes, Jason can defend the
12 deposition during the few minutes
13 that I'll be out. But if we break
14 at 3:30, it will eliminate the
15 time that I have to be away, if
16 that's okay.
17 MR. DAVIS: Let's still take
18 a five-minute break. Let's just
19 take a short break now. I might
20 be moving to different topics. So
21 I just want to collect my
22 thoughts.
23 MR. TRISCHLER: Sure.
24 MR. DAVIS: So why don't we

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[REDACTED]

12 Q. If that was done?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: Yeah. Again,
16 we've spoken about that. I think
17 validation is required with the
18 DMF.
19 MR. DAVIS: Do you want to
20 take a break? We've been going
21 quite a bit.
22 MR. TRISCHLER: Sure.
23 That's fine. Hey, John, can I ask
24 a favor?

Page 233

1 reconvene -- it's 2:45. Why don't
2 we reconvene at 2:50.
3 MR. TRISCHLER: Thank you.
4 THE VIDEOGRAPHER: The time
5 right now is 2:45 p.m., and we are
6 off the record.
7 (Short break.)
8 THE VIDEOGRAPHER: The time
9 right now is 2:56 p.m. We are
10 back on the record.
11 BY MR. DAVIS:
12 Q. So Mr. Glover, we've been
13 talking for a while about process
14 validation on recovered solvents, right?
15 A. Yep.
16 Q. And I don't want to put
17 words in your mouth, but -- and correct
18 me if I'm misstating any of this, but
19 what you're saying is that the process
20 validation work for recovered solvents
21 with regard to valsartan, that that was
22 done in the -- in the DMF workup,
23 correct?
24 [REDACTED]

Page 234

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 Q. Well, we've seen evidence
21 that -- you know, let's separate, you
22 know, the DMF versus the non-DMF. And
23 we've seen evidence that no process
24 validation work was done, right, after --

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1 excluding the DMF, we've seen e-mails
2 where individuals are saying that no
3 process validation work was done for
4 recovered solvents for valsartan, right?
5 MR. TRISCHLER: Objection.
6 Mischaracterizes the evidence.
7 THE WITNESS: The only thing
8 that I've seen is e-mails stating
9 that they're looking for a
10 recovered solvent validation
11 report.
12 And if Unit 8 combined it
13 with the valsartan validation,
14 then it's an argument on whether
15 you need a separate validation or
16 you can do them together.
17 BY MR. DAVIS:
18 Q. I mean, what's unclear about
19 someone saying we have not yet done any
20 recovered solvent validation at Unit 8?
21 What's unclear about that?
22 MR. TRISCHLER: Objection to
23 form.
24 [REDACTED]

Page 236

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 Q. Okay. Well, we can agree
24 that you've seen -- you don't have any

Page 237

1 evidence to suggest that Mylan, after the
2 DMF, did any process validation work on
3 recovered solvents. Can you point me to
4 anything?
5 A. I haven't looked for any.
6 Q. You haven't looked. I mean,
7 you're --
8 A. No, I don't have any in my
9 possession.
10 Q. This is a topic that you're
11 designated on, to testify on behalf of
12 Mylan. Do you understand that?
13 A. Sure.
14 Q. Okay. And what you're --
15 what you're -- what you're speculating is
16 that it's likely that that recovered
17 solvent validation work was done as part
18 of the DMF.
19 Can you explain to me what
20 work you would envisage being done in the
21 DMF for process validation if that was
22 done?
23 A. Again, it would be highly
24 speculative for me to, you know, speak to

Page 238

1 that. I can't say for certain how much
2 additional work or what kind of
3 additional work would have been done, but
4 I know extensive additional work is done
5 traditionally as part of DMF validation.
6 Q. And we talked about this
7 earlier. But just -- I mean, I think we
8 agreed on this actually, is that just
9 simply listing recovered solvents in the
10 master batch production record, it would
11 not be sufficient for process validation.
12 Simply just putting it in the recipe
13 doesn't mean it's validated, right?
14 MR. TRISCHLER: Objection.
15 Asked and answered.
16 THE WITNESS: Right. And
17 the validation itself will be
18 incorporated in the DMF and will
19 include some expanded testing and
20 a bunch of additional work,
21 customized per the synthetic
22 process. And that would also be
23 there in the DMF.
24 BY MR. DAVIS:

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1 Q. When you say expanded
2 testing, like testing for impurities, for
3 example?
4 A. Again, it varies case by
5 case. I can't say for certain what they
6 did for the valsartan DMF.
7 MR. DAVIS: I'm marking Tab
8 27 which is plaintiffs Exhibit 26.
9 (Document marked for
10 identification as Exhibit
11 PL-Glover-26.)
12 BY MR. DAVIS:
13 Q. Do you recognize this as the
14 FDA's establishment inspection report of
15 Unit 8 that was transmitted to Mylan on
16 or about March 4th, 2019, for inspection
17 dates of December 3rd to December 10,
18 2018?
19 A. Yeah.
20 Q. Okay. And this inspection
21 was triggered by Mylan's recall of its
22 valsartan that was manufactured at Unit 8
23 for API, right?
24 A. We have no reason to believe

Page 240

1 that. I don't think that was stated.
2 Q. I mean the inspection
3 related almost exclusively to Mylan's
4 valsartan API production, did it not?
5 A. I haven't read it
6 comprehensively, but again, I don't think
7 inspectors typically come in and tell you
8 if they're triggered based off of some
9 event.
10 Q. So you're the global head of
11 quality, and you haven't read fully this
12 FDA inspection report?
13 A. I read the 483 and the
14 response and I've scanned through the
15 EIR. But I don't believe you'll find
16 anywhere in here where they say, "We
17 triggered this inspection because of your
18 recall." That's not -- I've never seen
19 FDA do that before. Let's put it that
20 way.
21 Q. On Page 3 of 36 -- do you
22 see the numbering convention at the
23 bottom of the actual EIR?
24 A. Yeah.

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1 Q. Do you see, "Where it says
2 during the course of this inspection,
3 Mylan announced a consumer level
4 voluntary nationwide recall to include
5 all lots of valsartan-containing products
6 within expiry"?
7 A. Yep.
8 Q. Okay. Go to Page 18 of 36.
9 A. Okay.
10 Q. Sorry. I mean -- or yeah,
11 18 of 36. My apologies.
12 At the top full paragraph
13 there.
14 A. Okay.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 242

[REDACTED]

Page 244

[REDACTED]

12 Q. Well, with due respect, you
13 are the corporate designee on this. I
14 should be entitled to testimony from the
15 company on these questions.
16 Did you look into this at
17 all in preparing for your deposition?
18 A. I did not review the DMF
19 specific to fresh or recovered solvents,
20 no.
21 Q. And you didn't look to see
22 whether process validation was done in
23 any context in preparing for this
24 deposition, did you?

Page 243

[REDACTED]

Page 245

1 A. I did not review process
2 validation, no.
3 MR. DAVIS: I'm going to
4 mark Tab 28, which is now
5 Exhibit 27.
6 (Document marked for
7 identification as Exhibit
8 PL-Glover-27.)
9 BY MR. DAVIS:
10 Q. Before I move on to that,
11 there's one other thing that I want to
12 call to your attention in this EIR that's
13 on that same page, Page 19, which is the
14 last sentence of that paragraph.
15 "While discussing the
16 impurity situation with Dr. Gomes, he
17 stated that moving forward the firm will
18 evaluate their solvent recovery process,
19 including establishing limits on reuse
20 and enhanced risk assessment."
21 Did I read that correctly?
22 A. Yeah.
23 Q. Is Dr. Gomes admitting there
24 that Mylan did no process validation for

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1 its recovered solvents?

2 A. I don't read it that way at

3 all. What I'm understanding is that this

4 is right on the heels of the recall where

5 they identified opportunities to improve

6 the recovery process, and that's what

7 he's saying, is that they're going to

8 evaluate the recovery process and add the

9 additional controls as needed.

10 Q. I mean, don't you think that

11 would have been an appropriate place for

12 Dr. Gomes to tell the FDA, hey, we did do

13 process validation for recovered

14 solvents?

15 MR. TRISCHLER: Objection to

16 form.

17 THE WITNESS: It doesn't

18 appear to me like this paragraph

19 is discussing process validation

20 specifically. It looks like

21 they're talking about just

22 differences in the VAA, VST

23 process and the introduction of

24 the nitrosamines.

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1 BY MR. DAVIS:

2 Q. They are referring to fresh

3 o-xylene being used for the validation

4 batches and showing no levels of NDEA and

5 all subsequent and commercial batches

6 going to patients using recovered

7 solvents and containing NDEA.

8 Don't you read that that the

9 FDA calling attention to the fact that

10 Mylan only used fresh solvent in their

11 validation batches?

12 A. Yeah, I can't make that

13 correlation just from that sentence, no.

14 Q. What about enhanced risk

15 assessment? Dr. Gomes refers to enhanced

16 risk assessment. Do you know if he was

17 referring to any risk assessment that had

18 been done on recovered solvents?

19 A. Again, I don't know. I

20 would be purely speculating if I guessed

21 at what those words mean.

22 Q. But you're unaware of any

23 risk assessment that was done on

24 recovered solvents other than the draft

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1 risk assessments -- the two draft risk

2 assessments that we looked at, correct?

3 A. Right.

4 Q. And no risk assessments were

5 done, that you're aware of, that relate

6 specifically to valsartan or the

7 recovered solvents used in valsartan,

8 correct?

9 A. Again, yeah, I don't know of

10 any that were done historically. I think

11 you showed me one today earlier.

12 Q. As a result of this

13 inspection, this is where Mylan committed

14 to the FDA to not use recovered solvents

15 anymore for valsartan that we were

16 talking about?

17 MR. TRISCHLER: Objection to

18 form.

19 THE WITNESS: I think we had

20 already decided not to use

21 recovered solvents as a result of

22 the investigation. And we

23 included that information in our

24 response likely.

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1 BY MR. DAVIS:

2 Q. And that's what's in this

3 next paragraph, staying with the EIR on

4 Page 19, "Moving forward, the firm

5 intends" -- do you see that?

6 A. Yes.

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q. Look at the VAA process

19 below. "Mylan appears to be saying that

20 they are not going to use recovered

21 material from VST and VAA, but the firm

22 does permit itself to use recovered

23 material from VAA in subsequent VAA

24 batches."

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1 Is that currently being
2 done, or is what you told me earlier more
3 accurate, that VAA was not -- was also
4 not used in recovered materials or
5 solvents?
6 A. Again, I'm not sure about
7 the changeover time, but I know as of
8 today I don't believe they use any
9 recovered material.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 BY MR. DAVIS:
24 Q. Look at the next exhibit

Page 251

1 which I think I marked before moving back
2 to this one. Is there a number on that
3 one. It's Tab 28. I believe we are at
4 Exhibit 27 now.
5 MR. DAVIS: Is that
6 Exhibit 27?
7 MR. TRISCHLER: It is.
8 THE WITNESS: What -- yes.
9 The response to the 483? Is that
10 what you're marking as 27?
11 MR. DAVIS: That's correct.
12 BY MR. DAVIS:
13 Q. And Mr. Glover, you told me
14 that you were involved in drafting this
15 response earlier, correct?
16 A. Yes.
17 Q. Okay. Take a few moments to
18 review that and let me know when you are
19 ready to talk about it.
20 A. Okay.
21 Q. I want to direct your
22 attention to page -- Page 6 of 15.
23 You'll see the numbering in the top
24 right.

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1 A. Okay.
2 Q. There's a paragraph right
3 below the tables there. It says, "We
4 have included specific CAPAs and amended
5 our batch manufacturing records of VST
6 and VAA processes so as to control
7 recovered solvent usage. In case of VST
8 process, the recovered solvent usage is
9 eliminated as triethylamine is used in
10 the process; therefore, the risk of
11 impurity introduction through recovered
12 solvent usage is high."
13 Do you see that?
14 A. Yeah.
15 Q. You were involved in
16 drafting that response to the FDA's
17 observation there?
18 A. Yeah.
19 Q. Okay. And the risk of
20 impurity introduction through recovered
21 solvent use is high when triethylamine is
22 used because of its ability to interact
23 with nitrosating agents, such as sodium
24 nitrite and hydrochloric acid, correct?

Page 253

1 A. Sorry. Could you repeat
2 that?
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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1 I thought we saw a draft from 2012.
2 Q. No. We saw an e-mail from
3 2012 where somebody was asking if there
4 were any concerns.
5 I think you'd agree that
6 that doesn't qualify as a risk
7 assessment, correct?
8 A. Now you're confusing me. I
9 thought we had a risk assessment for
10 recovered solvents from 2012. Are you
11 asking --
12 Q. You may be referring to the
13 draft one from 2014 that we looked at?
14 A. Oh, I'm sorry. Maybe it is
15 '14.
16 Q. And that one did not relate
17 specifically to valsartan or any of the
18 recovered solvents as we saw, right?
19 A. Fair enough.
20 Q. There's -- it says a number
21 of times in this 483 response -- let me
22 find an example of it.
23 If you go back to the page
24 before, in the middle of that first

[REDACTED]

21 Q. Well, there was no risk
22 assessment done, was there, for valsartan
23 and recovered solvents?
24 A. I'm not sure of that either.

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1 paragraph on -- this is Page 5 of 15.
2 "As the formation of this impurity is
3 occurring outside the primary synthetic
4 process, the presence of this impurity in
5 the API was not anticipated."
6 Do you see that?
7 A. Yeah.
8 Q. Factually, that was --
9 that's correct, right, that Mylan
10 factually did not anticipate the
11 impurity?
12 A. That is correct.
13 Q. Don't you think it should
14 have been anticipated though?
15 MR. TRISCHLER: Objection to
16 the extent that it's beyond the
17 scope. Objection to form.
18 THE WITNESS: Yeah, I wasn't
19 involved in development. I think
20 it's probably inappropriate for me
21 to speculate on what the
22 development team should or should
23 not have anticipated.
24

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1 BY MR. DAVIS:
2 Q. Do you think that if Mylan
3 had done a risk assessment specifically
4 related to valsartan and the use of
5 recovered solvents in valsartan, or had
6 done process validation of its recovered
7 solvents, that it would have been more
8 likely that Mylan could have anticipated
9 this?
10 MR. TRISCHLER: Objection to
11 form.
12 THE WITNESS: Yeah, I have
13 no way of, again -- again, you
14 speculate so much in that sentence
15 that it sounds like you're
16 basically saying, if we had done
17 everything we did in the
18 comprehensive investigation on the
19 heels of FDA's findings, would we
20 have found this.
21 BY MR. DAVIS:
22 Q. That's not what I'm saying.
23 I'm saying -- I'm saying had Mylan done a
24 risk assessment at the time or had they

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1 done process validation at the time,
2 isn't that the reason that those things
3 exist in quality assurance? Why else is
4 risk assessment done?
5 MR. TRISCHLER: Objection to
6 the form of the question.
7 THE WITNESS: My
8 understanding is that upon first
9 contact from FDA in July, we did
10 do a risk assessment. So did FDA.
11 We both concluded there was no
12 risk of nitrosamine impurities.
13 And so any further
14 speculation about what could have
15 or should have been done is purely
16 that, speculation.
17 BY MR. DAVIS:
18 Q. You're talking about a risk
19 assessment post-recall, correct?
20 A. No, no. I'm talking about
21 the first attempt to understand the risk
22 in July of 2018, whenever -- the very
23 first conversation on NDMA started.
24 Q. Well, at that point Mylan

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1 had been using recovered solvents for
2 years at that point in valsartan,
3 correct?
4 A. Yeah.
5 Q. I'm asking, at the time, you
6 know, Mylan made that decision to start
7 using recovered solvents, shouldn't a
8 risk assessment have been done. Isn't
9 that why risk assessments exist, is to
10 identify these exact issues?
11 MR. TRISCHLER: Objection.
12 Asked and answered.
13 THE WITNESS: The use of the
14 recovered solvent was established
15 based on the established
16 acceptance criteria, which was
17 filed within the DMF for both
18 fresh and recovered solvents. We
19 understood the risk to be
20 negligible based on the assumption
21 that we were going to get pure
22 solvent back. And we were testing
23 every batch incoming.
24

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1 BY MR. DAVIS:
2 Q. Testing every batch --
3 MR. TRISCHLER: John, I need
4 to -- I need to take that break.
5 MR. DAVIS: Okay. All
6 right. That's fine. Clem,
7 15 minutes?
8 MR. TRISCHLER: Yeah. If
9 I'm not done by 3:45, I'll have --
10 Jason will sign in and you guys
11 can start at that time, okay?
12 Because I don't want to hold it
13 up. But I'm hoping to be done.
14 Okay?
15 MR. DAVIS: Okay. Sounds
16 good.
17 MR. TRISCHLER: Appreciate
18 it.
19 THE VIDEOGRAPHER: The time
20 right now is 3:28 p.m., and we're
21 off the record.
22 (Short break.)
23 THE VIDEOGRAPHER: The time
24 right now is 3:48 p.m., and we are

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1 back on the record.
2 MR. DAVIS: Michelle, I've
3 forgotten where we left off during
4 the break.
5 Is there any chance that you
6 can read back the last question
7 and answer?
8 (Whereupon, the court
9 reporter read back the requested
10 portion of testimony.)
11 BY MR. DAVIS:
12 Q. Okay. Yes or no,
13 Mr. Glover. Are you aware of a risk
14 assessment that was done at any point
15 prior to being contacted about potential
16 nitrosamine contamination that
17 specifically related to recovered
18 solvents and valsartan?
19 A. Again, I really don't think
20 it's a yes or no question. I mean, the
21 risk evaluation is incorporated within
22 the DMF. The development, the
23 submission, everything about the process
24 validation is conducted, is also risk

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1 evaluation.
2 The risk assessment in the
3 format that you looked at, I'm not aware
4 of any other old risk assessments. That
5 format may not have even existed back in
6 2012 to '14. So I can't say for certain
7 what -- or what elements of risk
8 evaluation were performed.
9 Q. So aside from what you
10 contend may be in the DMF, you're not
11 aware of any risk assessment that was
12 done regarding valsartan and recovered
13 solvents, correct?
14 A. Separate from the
15 development and validation conducted in
16 support of the DMF, I'm not aware of any
17 other supplemental risk assessment.
18 Q. And you're not aware of what
19 validation work was actually done in the
20 DMF either, are you?
21 A. Only that I know something
22 had to be done or it wouldn't be
23 approved.
24 Q. Or maybe it wasn't

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1 disclosed?
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: Then it
5 wouldn't be approved.
6 BY MR. DAVIS:
7 Q. You mentioned a risk
8 assessment that was done after the
9 nitrosamine issue was raised, correct?
10 A. You're talking about in
11 July, August of 2018?
12 Q. Right. And beyond.
13 A. Yes, and again, I want to be
14 careful with your use of the word "risk
15 assessment." It may or may not take the
16 shape of that document that you've gotten
17 used to looking at. It could be in many
18 forms.
19 But there was an evaluation
20 of nitrosamine risk performed early in
21 the process in -- I think it was July of
22 '18 when NDMA was first uncovered, and
23 this was done by both Mylan and the FDA.
24 Q. And Mylan actually at that

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1 time found that there was no risk of
2 nitrosamine contamination, correct?
3 A. Correct. That was
4 corroborated by the FDA as well.
5 Q. Based on what they knew,
6 correct?
7 A. Based on what both of us
8 knew, yes.
9 Q. Let me show you -- I'm not
10 sure if this is documents that I provided
11 today. I didn't intend to use them
12 today. But --
13 MR. DAVIS: Clem, how
14 fast -- how fast could you print
15 out a one-page e-mail and
16 three-page attachment?
17 MR. TRISCHLER: Two minutes.
18 MR. DAVIS: Sure. Can we do
19 that, because I'm going to
20 e-mail --
21 MR. TRISCHLER: Did you send
22 it to me?
23 MR. DAVIS: Yes.
24 MR. TRISCHLER: Okay. When

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1 did you send it, John? Because
2 I'm not finding it.
3 MR. DAVIS: Oh, I'm sending
4 it right now.
5 MR. TRISCHLER: Oh. All
6 right.
7 MR. DAVIS: I'm going to
8 keep going. Clem, can you have
9 somebody print these, and you can
10 let me know when you have printed
11 copies.
12 MR. TRISCHLER: Yeah. I
13 still haven't received an e-mail.
14 But I'll keep an eye out for it.
15 MR. DAVIS: It should be
16 coming right now.
17 MR. TRISCHLER: All right.
18 Go ahead.
19 MR. DAVIS: I'm going to
20 mark Tabs 59 and 60.
21 59 is Exhibit 28.
22 (Document marked for
23 identification as Exhibit
24 PL-Glover-28.)

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1 MR. DAVIS: 60, is
2 Exhibit 29.
3 (Document marked for
4 identification as Exhibit
5 PL-Glover-29.)
6 BY MR. DAVIS:
7 Q. Let me know when you have
8 those in front of you, Mr. Glover.
9 A. I have them both.
10 Q. Do you recognize -- do you
11 recognize Exhibit 29 as the 2019 EIR of
12 Unit 8?
13 A. Yes.
14 Q. And the previous exhibit is
15 the FDA's transmittal e-mail of that EIR,
16 correct?
17 A. Yeah.
18 Q. And that occurred in June of
19 2020?
20 A. Yes.
21 Q. Take a look at Page 3 or --
22 sorry, page -- the numbering is on the
23 bottom right corner. Page 2.
24 A. Sorry. Say the page number

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1 again.
2 Q. Actually spilling into the
3 top of Page 1.
4 So basically the first
5 numbered page, Page 1, at the very bottom
6 and spilling over into Page 2.
7 A. Okay.
8 Q. Have you seen this EIR
9 before?
10 A. I have.
11 Q. Have you read it?
12 A. Not comprehensively, no.
13 Q. Okay. At the bottom of Page
14 1, the FDA references, "The previous FDA
15 inspection was conducted 12/3 to
16 12/10/2018 and resulted in the issuance
17 of a three-item FDA Form 483."
18 Do you see that?
19 A. Yeah.
20 Q. And then the third bullet,
21 one of those three items is, "The
22 analytical methods used to determine
23 purity, strength, quality, and identity
24 of drug substances are not the same as

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1 the conditions in which they were
2 validated."
3 Did I read that correctly?
4 A. Yep.
5 Q. And then below that, the FDA
6 says, "The firm did not fully resolve the
7 earlier deficiencies such that all three
8 observations were repeat observations in
9 the current inspection."
10 Did I read that correctly?
11 A. Yes.
12 Q. Okay. Go to Page 8.
13 A. Okay.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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1 recovered solvents and the use of sodium
2 nitrite?
3 A. I don't think that's what
4 that means. I think what he's trying to
5 say is that he disagreed with our
6 approach to cleaning of shared equipment.
7 If you read Observation 2 his focus is on
8 the potential for cross-contamination
9 within this facility.
10 He uses the general terms
11 "risk assessment." But what he's really
12 talking about is our understanding of
13 cross-contamination.
14 We did not agree with this
15 observation. His whole premise was based
16 on an argument that we should have been
17 testing for swab residue samples. We had
18 a scientific argument why we didn't feel
19 that was necessary.
20 You know, this was just a --
21 it's FDA's opinion, the inspector's
22 opinion, based on what he saw.
23 Q. Well look at -- look at the
24 bottom of page -- or sorry. Look at Page

[REDACTED]

20 Q. So the FDA is telling Mylan
21 that it had still not done an adequate
22 risk assessment, almost two years after
23 learning of not only the nitrosamine
24 contamination, but what caused it, namely

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1 17.
2 A. Okay.
3 Q. The last paragraph of the
4 production system section. Let me know
5 when you're there.
6 A. I think I'm there. You are
7 talking about, "I focused"?
8 Q. Yes. "I observed that the
9 firm's investigation was inadequate such
10 that the firm did not evaluate the risk
11 associated with using sodium nitrite in
12 the solvent recovery systems and the
13 cleaning validation with respect to NDMA
14 and NDEA contaminations."
15 A. Yes. The words -- "the
16 cleaning validation" -- well, the
17 cleaning validation piece is what he was
18 focused on.
19 Q. To me it sounds like he's
20 focused on both.
21 MR. TRISCHLER: Objection to
22 form.
23 THE WITNESS: We were with
24 the inspector. And he was very

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1 clear that in his mind, because of
2 the nitrosamine presence, that the
3 cleaning validation should have
4 taken that into consideration, and
5 he wanted to see a very specific
6 test being performed, which we
7 argued scientifically was
8 unnecessary.
9 BY MR. DAVIS:
10 Q. What test was that?
11 A. A swab recovery test, a swab
12 residue test for nitrosamine itself as
13 opposed to the intrinsic carrier
14 molecule.
15 Q. What's the intrinsic carrier
16 molecule?
17 A. It depends on the stage, but
18 if you have a contamination and you
19 clean, you can test for the residue of
20 the highest concentration, and then you
21 can back calculate the relative potential
22 carryover.
23 It would have been
24 impossible to test for nitrosamine

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1 reliably at the levels that would have
2 been supposedly present in the residue
3 after cleaning.
4 Still to this day, that's
5 the case. It's more reliable to test for
6 the actual analyte of interest or the
7 intrinsic carrier molecule. And that's
8 still what we do. We added this
9 nitrosamine test to satisfy the FDA, but
10 it's a meaningless test.
11 Q. How does that work with
12 regard to Mylan's use of contract
13 manufacturing units to actually do the
14 solvent recovery?
15 A. It had nothing to do with
16 it. It had to do with shared equipment
17 within the facility itself.
18 And his concerns that any
19 shared equipment within the facility
20 needed to be cleaned to a definition
21 based on his interpretation.
22 Q. Within Mylan --
23 A. -- cleaning being --
24 MR. TRISCHLER: Let him

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1 finish, John.
2 MR. DAVIS: Yeah. Sorry. I
3 didn't mean to cut you off.
4 THE WITNESS: No, just clean
5 being defined by the results of
6 swab testing, which we always did
7 and still contend that our swab
8 testing was the most appropriate
9 way to verify cleaning.
10 MR. TRISCHLER: John, I have
11 the other exhibits, or those other
12 documents that you asked to be
13 copied.
14 MR. DAVIS: Okay. Let's
15 look at those.
16 All right. I'm introducing
17 Tab 64 as Exhibit 30.
18 (Document marked for
19 identification as Exhibit
20 PL-Glover-30.)
21 MR. DAVIS: And Tab 65 as
22 Exhibit 31.
23 (Document marked for
24 identification as Exhibit

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1 PL-Glover-31.)
2 BY MR. DAVIS:
3 Q. This is an e-mail --
4 Exhibit 30 is an e-mail on March 20,
5 2019, which -- does that remind you -- or
6 do you recall that the EIR from Unit 8
7 for the December 2018 inspection was
8 delivered to Mylan just before this?
9 A. Okay.
10 Q. And the subject of the
11 e-mail is "Backup for FDA call."
12 Do you see that?
13 A. Okay.
14 Q. And then there's an
15 attachment, Valsartan-FDA.docx.
16 Do you see that?
17 A. I do.
18 Q. Exhibit 31 is that
19 attachment.
20 A. Yep.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 Q. Does that remind you that
8 recovered solvents were not validated as
9 part of Mylan's DMFs for valsartan?
10 A. Again, our understanding of
11 the DMF filing is that it currently
12 includes the recovered solvent
13 referenced.
14 You know, I can't say for
15 certain whether it was in the original
16 DMF filing or whether it was subsequently
17 amended.
18 I haven't done that
19 research.
20 Q. Amended after discovery of
21 nitrosamine contamination, correct?
22 A. I have no idea.
23 Q. I mean, do you have any
24 reason to doubt what this document says?

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1 A. Oh, sure. I mean, I don't
2 necessarily know who even wrote it.
3 Q. Well, it's from Dr. Gomes,
4 who you say you speak to every day and
5 reports directly to you, isn't it?
6 A. I don't know if it came from
7 him or it's attached by one of the other
8 folks that are on here. Again, I have no
9 way of validating the statement.
10 Q. Well, Dr. Gomes is sending
11 it to Walt Owens and says, "Here is your
12 backup for the FDA call."
13 I mean, clearly he approved
14 what was in it, correct, even if he
15 didn't write it?
16 A. Understood.
17 Q. Okay. Do you have any
18 reason to doubt that Dr. Gomes is
19 accurately conveying that, "Solvent
20 recovery processes were not any part of
21 our API DMFs"?
22 A. Yes, because I understand
23 that at least in one case it is there.
24 So I just don't know the details on when

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1 or how it is there, so...
2 Q. How -- where did you come to
3 that understanding from?
4 A. Through various discussions
5 in the past two months.
6 Q. With who?
7 A. With Dr. Gomes.
8 Q. You don't think Dr. Gomes
9 would encourage Walt Owens to lie to the
10 FDA about something, right?
11 MR. TRISCHLER: Objection to
12 form.
13 THE WITNESS: I mean, I
14 don't even know how to answer
15 that. No one would encourage
16 someone to lie to the FDA.
17 BY MR. DAVIS:
18 Q. I mean, this is a -- I mean,
19 did you read the context of this e-mail,
20 and attachment based on the title of the
21 document is valsartan-FDA and the e-mail
22 being "Backup For FDA Call," that these
23 are talking points to deliver to the FDA?
24 A. I understand this is

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1 background for a discussion, yes.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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11 MR. DAVIS: I'm marking Tab
12 71 as Exhibit 32.

13 (Document marked for
14 identification as Exhibit
15 PL-Glover-32.)

16 THE WITNESS: Okay.

17 BY MR. DAVIS:

18 Q. Who is Denise Mercer?

19 A. I'm not sure. She works for
20 Mylan.

21 Q. If you go to Page 3 of this
22 attachment -- or sorry, this e-mail,
23 you'll see an e-mail from her that's
24 dated July 25th, 2019.

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1 Do you see that?

2 A. Yes.

3 Q. And then it actually has her
4 e-card down there. She is an API senior
5 specialist, it appears, at Morgantown.

6 She says, "Per the guidance,
7 Mylan's FDA 356h form must include all
8 facilities related to the manufacture of
9 the API, i.e., micronization sites,
10 contract laboratory testing sites, all
11 cGMP storage warehousing facilities, et
12 cetera."

13 Do you see that?

14 A. Yes.

<p>Page 286</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

[illegible]

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1 have we been on so far?
2 MR. TRISCHLER: My
3 calculation is about five and a
4 half.
5 THE VIDEOGRAPHER: Exactly
6 five hours, 30 minutes.
7 MR. TRISCHLER: Hey, pretty
8 good.
9 I'm fine with -- I guess
10 I -- I guess I should talk to
11 Mr. Glover. I was going to say
12 I'm fine to take a break and
13 continue for another hour or so.
14 But what --
15 MR. DAVIS: Let's take a
16 break. I'll send the document --
17 actually, we can go off the record
18 so you you're not having to take
19 this down, Michelle. Sorry about
20 that.
21 THE VIDEOGRAPHER: The time
22 right now is 4:26 p.m., and we're
23 off the record.
24 (Short break.)

Page 298

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 MR. DAVIS: I'm going to
21 move to Tab 76, which is now
22 marked as Plaintiffs' Exhibit 34.
23 (Document marked for
24 identification as Exhibit

Page 299

1 PL-Glover-34.)
2 BY MR. DAVIS:
3 Q. The first page is just a
4 slip page, by the way. I don't know if
5 I've explained this yet. That's just a
6 page that produces the file path as it
7 was given to us. It's not part of the
8 document. It just includes the file
9 path -- like, some of the metadata that
10 we talked about.
11 If you go to the first --
12 it's a one-page document by itself. And
13 do you see that it's on Matrix headers?
14 A. I do.
15 Q. Okay. Do you see the date
16 of April 13, 2011?
17 A. Yeah.
18 Q. Does this look like to you
19 that it's an approval form for using
20 Lantech for recovered solvent?
21 A. It appears to be a
22 evaluation report.
23 Q. And the evaluation comments
24 and handwriting say, "Facility is

Page 300

1 suitable to carry out recovery activity
2 of o-xylene for valsartan for Unit 8"?
3 A. Right.
4 Q. Do you know if any other
5 evaluation was actually done of Lantech
6 other than what's reflected in this
7 document, which is checking a few boxes?
8 MR. TRISCHLER: Objection to
9 form.
10 THE WITNESS: Yeah, no, I am
11 not aware or don't know of what
12 else would be out there or what
13 they've done.
14 MR. DAVIS: Actually, I'm
15 going to show you Tab 77 which is
16 Exhibit 35.
17 (Document marked for
18 identification as Exhibit
19 PL-Glover-35.)
20 BY MR. DAVIS:
21 Q. The title of this document
22 is "Contract Manufacturer Evaluation
23 Report Review Based on Inspection."
24 Do you see that.

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1 A. Yep.
2 Q. And it lists the company
3 name as Lantech. It lists the date of
4 inspection as January 25th, 2011.
5 Do you see that?
6 A. Yeah.
7 Q. And then there's a
8 multiple-page checklist that follows.
9 Do you see that?
10 A. Yep.
11 Q. Number 8 is, "Lab testing
12 facilities found to be adequate."
13 And that's checked yes,
14 correct?
15 A. Yes.
16 Q. Number 10 is, "The
17 production and quality assurance
18 departments are independent." Yes.
19 Do you see that?
20 A. Yes.
21 Q. Number 11 on the next page,
22 "Quality assurance system program is
23 functional." Yes.
24 Do you see that?

Page 302

1 A. Yes.
2 Q. Number 14, "Product failures
3 are reviewed." Yes.
4 Do you see that?
5 A. Yes.
6 Q. Number 23, "Quality control
7 procedures are available and followed."
8 Yes.
9 Do you see that?
10 A. Yeah.
11 Q. Number 27, "Quality control
12 is independent of production and
13 decisionmaking." Yes.
14 Do you see that?
15 A. Yes.
16 Q. Number 33, "Validation
17 programs for methods, instruments,
18 personnel are available."
19 Do you see that?
20 A. Yes.
21 Q. 36, "Testing of raw
22 materials is done prior to release or use
23 in production."
24 Do you see that?

Page 303

1 A. Yep.
2 Q. And that's checked yes also?
3 A. Yeah.
4 Q. 40C, "Following our
5 available validation (process, cleaning
6 and method)." Yes.
7 Do you see that?
8 A. Yeah.
9 Q. 45, "Segregation of area is
10 done to prevent cross-contamination."
11 Yes.
12 Do you see that?
13 A. Yeah.
14 Q. So Mylan found Lantech
15 adequate in all these areas, at least
16 according to its inspection done in 2011,
17 correct?
18 A. Yeah.
19 MR. DAVIS: I'm marking Tab
20 74, which is Plaintiffs'
21 Exhibit 36.
22 (Document marked for
23 identification as Exhibit
24 PL-Glover-36.)

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1 BY MR. DAVIS:
2 Q. Do you see the approved date
3 on this? It appears to be November 28th,
4 2013.
5 A. Yeah.
6 Q. Did you catch my question
7 there?
8 A. I'm sorry. I said yes.
9 Q. Oh. Okay. Sorry about
10 that.
11 Again, this document is
12 related to Lantech, and it's called
13 "Contract Manufacturer General
14 Information Form."
15 Have you seen this document
16 before?
17 A. I have not.
18 Q. Okay. And the person who's
19 signing it here from Mylan is part of
20 Mylan's quality assurance department, is
21 he not? Is he not?
22 A. It's very hard to tell. I
23 mean, I see a header that says corporate
24 QA India. And then his -- yeah, his

Page 305

1 designation is GM-CQA. I can only assume
2 that's quality.
3 Q. Do you not know whether that
4 designation is part of quality assurance?
5 A. I can't say definitively. I
6 would have to again defer to Dr. Gomes.
7 He would know better than me.
8 Q. Okay. If you go to the next
9 page. Do you see Numbered 14, "Is the
10 facility approved by any regulatory
11 agencies? (USFDA/MHRA/EDQM/TGA, et
12 cetera)"?
13 A. Yeah.
14 Q. Do you see where no is
15 checked there?
16 A. Yes.
17 Q. What does that mean?
18 A. I don't know. I haven't
19 seen the form before. I'm not sure how
20 they interpret that.
21 Q. I assume I should talk to
22 Dr. Gomes about that also?
23 A. Yep.
24 ■ ■ ■

<p>Page 306</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 310</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 314</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>1</p> <p>Page 318</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 322</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 326</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 330</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

9 MR. DAVIS: I'm marking Tab
10 78 as Plaintiffs' Exhibit 38.
11 (Document marked for
12 identification as Exhibit
13 PL-Glover-38.)
14 THE WITNESS: Okay.
15 BY MR. DAVIS:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<p>Page 338</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

Page 342

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 MR. TRISCHLER: Hey, John.
8 It's about 6 o'clock. So I'd like
9 to adjourn, per the deposition
10 protocol. Okay?
11 MR. DAVIS: Yep. That's
12 fine. We can pick it back up on
13 Thursday.
14 MR. TRISCHLER: We starting
15 at 9:00 a.m. again?
16 MR. DAVIS: That's fine with
17 me.
18 Mr. Glover, does that work
19 for you?
20 THE WITNESS: Yes, sir.
21 MR. DAVIS: Are we off the
22 record?
23 THE VIDEOGRAPHER: One
24 second.

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1 The time right now is
2 5:56 p.m., and we're off the
3 record.
4 (Excused.)
5 (Deposition adjourned at
6 approximately 5:56 p.m.)
7
8
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Page 344

1
2 CERTIFICATE
3
4
5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.
9
10 It was requested before
11 completion of the deposition that the
12 witness, RICHARD DEREK GLOVER, have the
13 opportunity to read and sign the
14 deposition transcript.
15
16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: March 16, 2021
22
23 (The foregoing certification
24 of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

Page 345

1 INSTRUCTIONS TO WITNESS
2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.
8 After doing so, please sign
9 the errata sheet and date it.
10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.
14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.
21
22
23
24

Page 346

1 - - - - -
2 E R R A T A
3 - - - - -

4 PAGE LINE CHANGE

5 _____

6 REASON: _____

7 _____

8 REASON: _____

9 _____

10 REASON: _____

11 _____

12 REASON: _____

13 _____

14 REASON: _____

15 _____

16 REASON: _____

17 _____

18 REASON: _____

19 _____

20 REASON: _____

21 _____

22 REASON: _____

23 _____

24 REASON: _____

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1

2 ACKNOWLEDGMENT OF DEPONENT

3

4 I, _____, do

5 hereby certify that I have read the

6 foregoing pages, 1 - 348, and that the

7 same is a correct transcription of the

8 answers given by me to the questions

9 therein propounded, except for the

10 corrections or changes in form or

11 substance, if any, noted in the attached

12 Errata Sheet.

13

14

15 _____

16 RICHARD DEREK GLOVER DATE

17

18

19 Subscribed and sworn

20 to before me this

21 _____ day of _____, 20 ____.

22 My commission expires: _____

23 _____

24 Notary Public

Page 348

1 LAWYER'S NOTES

2 PAGE LINE

3 _____

4 _____

5 _____

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10 _____

11 _____

12 _____

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14 _____

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17 _____

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23 _____

24 _____

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Exhibit 92

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 - - -

5 IN RE: VALSARTAN, : MDL NO. 2875
6 LOSARTAN, AND :
7 IRBESARTAN PRODUCTS : CIVIL NO.
8 LIABILITY LITIGATION : 19-2875
9 : (RBK/JS)

10 :
11 THIS DOCUMENT APPLIES : HON. ROBERT
12 TO ALL CASES : B. KUGLER

13 - CONFIDENTIAL INFORMATION -
14 SUBJECT TO PROTECTIVE ORDER

15 - - -

16 April 9, 2021

17 - - -

18 Videotaped remote deposition of
19 ANTONY RAJ GOMAS, Ph.D., taken pursuant
20 to notice, was held via Zoom
21 Videoconference, beginning at 2:30 p.m.,
22 India Standard Time, on the above date,
23 before Michelle L. Gray, a Registered
24 Professional Reporter, Certified
 Shorthand Reporter, Certified Realtime
 Reporter, and Notary Public.

 - - -

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Testimony of:

ANTONY RAJ GOMAS, Ph.D.

By Mr. Davis 16

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<p style="text-align: right;">Page 14</p> <p style="text-align: center;">- - - DEPOSITION SUPPORT INDEX - - -</p> <p>Direction to Witness Not to Answer PAGE LINE None.</p> <p>Request for Production of Documents PAGE LINE None.</p> <p>Stipulations PAGE LINE None.</p> <p>Questions Marked PAGE LINE None.</p>	<p style="text-align: right;">Page 16</p> <p>before speaking to ensure all parties are heard completely.</p> <p>All counsel will be noted on the stenographic record.</p> <p>The court reporter is Michelle Gray and she will now swear in the witness.</p> <p style="text-align: center;">- - -</p> <p>... ANTONY RAJ GOMAS, Ph.D., having been first duly sworn, was examined and testified as follows:</p> <p style="text-align: center;">- - -</p> <p>THE VIDEOGRAPHER: Please proceed.</p> <p style="text-align: center;">- - -</p> <p>EXAMINATION</p> <p style="text-align: center;">- - -</p> <p>BY MR. DAVIS:</p> <p>Q. Good morning, Dr. Gomas. We met briefly off the record. For the record, it's good morning my time. It's good afternoon your time.</p> <p>Can you just tell me where you're located right now?</p>
<p style="text-align: right;">Page 15</p> <p style="text-align: center;">- - -</p> <p>THE VIDEOGRAPHER: Good afternoon. We are now on the record.</p> <p>My name is Bill Geigert. I'm a videographer for Golkow Litigation Services.</p> <p>Today's date is April 9th, 2021. And the time is 2:30 p.m.</p> <p>This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation for the United States District Court for the District of New Jersey.</p> <p>The deponent is Dr. Antony Raj Gomas.</p> <p>All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.</p> <p>Due to the nature of remote reporting, please pause briefly</p>	<p style="text-align: right;">Page 17</p> <p>A. I'm located in Hyderabad, India.</p> <p>Q. And are you at Mylan Laboratories Limited headquarters?</p> <p>A. Yes, sir.</p> <p>Q. Okay. Is there anyone else in the room that you're sitting in?</p> <p>A. I have my counsel, Savitha, sitting in the room.</p> <p>Q. Okay. Anyone else?</p> <p>A. No, sir.</p> <p>Q. Okay. Do you have any screens open in front of you other than the one that has the camera on it?</p> <p>A. No.</p> <p>Q. Per our protocol here -- obviously, we're in a new world with Zoom depositions. I'll just ask that any chat windows or text message functions, any kinds of methods of communication textwise, that those be shut off and you not look at any of those while we are on the record. Is that fair?</p> <p>A. Absolutely none. Thank you.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. Okay. Thank you. 2 Have you given a deposition 3 before, Dr. Gomas? 4 A. No. This is the first one. 5 Q. Okay, great. So I guess let 6 me -- I think Clem and the videographer 7 put it pretty well. The rules are pretty 8 simple. Let's just, the main one is 9 let's try not to talk over each other. 10 It can be difficult in person sometimes. 11 It can be even more difficult on Zoom. 12 I'll do my best not to cut 13 you off. Sometimes I'm not very good at 14 that. 15 If you'll wait for me to 16 finish my question as well, that will 17 especially help Michelle Gray, who's our 18 court reporter today. 19 So with that, do you have 20 any questions about how we'll proceed 21 today? 22 A. No, sir. Thank you. 23 Q. Okay. Thanks. What's your 24 educational background, Dr. Gomas?</p>	<p style="text-align: right;">Page 20</p> <p>1 have a resumé or a CV, a curriculum vitae 2 that you have? 3 A. I haven't printed one yet. 4 But maybe on the break I could, if it is 5 okay, I could take it and then provide 6 you that information. 7 Q. Sure. That would be 8 fantastic. If you wouldn't mind. 9 A. Thank you. 10 Q. We'll probably take a break 11 in about an hour. 12 A. Certainly. 13 Q. That's sort of protocol. If 14 you wouldn't mind doing that, that would 15 be fantastic. 16 A. Certainly. 17 Q. When you -- what year did 18 you earn your Ph.D., about? 19 A. It's in the years, somewhere 20 in the year 2009 or '10, something, that 21 time frame, while working. 22 Q. Okay. And did you have a 23 professional career before earning your 24 Ph.D. or was that the --</p>
<p style="text-align: right;">Page 19</p> <p>1 A. I have a Ph.D. in analytical 2 chemistry, specialization. 3 Q. Okay. Where did you get 4 that from? 5 A. From India, university in 6 India. 7 Q. What is the name of the 8 university? 9 A. It is from a city situated 10 in Andhra Pradesh. Yeah. Andhra 11 Pradesh. 12 Q. And what was -- it's in an 13 Andhra Pradesh. But what is the name of 14 the university again? 15 A. It is called -- I can't 16 recall the name because it is an initial. 17 So... 18 Q. Oh, okay. What are the 19 initials? 20 A. No, that's what I meant, the 21 initials. My apologies, I'm not able to 22 recall the initials. 23 Q. Do you have -- sorry, I 24 didn't mean to cut you off there. Do you</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yes. 2 Q. Okay. What did you do 3 before earning that Ph.D.? 4 A. I was always working in the 5 pharmaceutical quality field. 6 Q. Since what year did you 7 start working in pharmaceutical quality? 8 A. I think it is somewhere in 9 1987 or so. 10 Q. Can you give me a brief 11 narrative of the companies that you 12 worked for -- well, let me strike that 13 and start this way. 14 About how many 15 pharmaceutical companies have you worked 16 for since 1987? 17 A. Including here at 18 Mylan/Viatrus, it is four. 19 Q. Four. Okay. Let's go 20 through those if you don't mind. In 1987 21 when you got started in the field, what 22 company did you go work for? 23 A. I started my career with a 24 company called Cipla. And then I worked</p>

Page 22

1 for that organization for 15 years in
2 quality. And then --
3 Q. So until about 2002, you
4 worked for Cipla?
5 A. I worked until 1995.
6 Q. 1995?
7 A. 1990 -- no, sorry. 2003.
8 Q. 2003, okay.
9 A. Yes.
10 Q. What was your role at Cipla
11 between '87 and 2003?
12 A. So I started as a laboratory
13 QC analyst. And then I grew up in the
14 organization. And when I left the
15 organization, I was the head quality
16 control for one of the sites.
17 Q. Was the division between
18 quality control and quality assurance at
19 Cipla similar to what it is at Mylan
20 currently?
21 MR. TRISCHLER: Objection to
22 the form of the question.
23 And you may answer.
24 And Dr. Gomas, occasionally

Page 23

1 I may have legal objections to
2 John's questions.
3 Most times, unless and in
4 rare circumstances, unless I
5 instruct you not to answer, you
6 should try to, you know, just
7 ignore my objections. They're for
8 the judge to resolve, perhaps at
9 some other point in time.
10 But what I would just ask --
11 again, it's a Zoom thing -- if you
12 can pause a little bit to give me
13 an opportunity to put that
14 objection on the record before you
15 answer Mr. Davis' questions.
16 Okay?
17 THE WITNESS: Thank you.
18 BY MR. DAVIS:
19 Q. Sure. So let me -- given
20 that, so basically what Clem is saying,
21 is if he -- as long as he doesn't
22 instruct you not to answer, if he places
23 an objection on the record, you're still
24 required to answer the question, if that

Page 24

1 makes sense.
2 So let me repeat the
3 question for you since it's been a little
4 bit.
5 Was the division of
6 responsibility of the QC department at
7 Cipla between quality control and quality
8 assurance, was that similar to the
9 division between quality assurance and
10 quality control at Mylan?
11 MR. TRISCHLER: Same
12 objection.
13 THE WITNESS: In Cipla, the
14 quality control, like any other
15 industry, quality division is
16 having two sections, QC and QA.
17 And there is a head who is from
18 quality who manages both. That is
19 pretty much the industry standard,
20 at least in India.
21 BY MR. DAVIS:
22 Q. Okay. So the quality
23 control at Cipla that you worked in, that
24 was more like laboratory quality control?

Page 25

1 A. That's right.
2 Q. What city were you based in
3 at Cipla?
4 A. Initially I started my
5 career in Bombay. I worked there for
6 five years.
7 Q. And then?
8 A. Then go to Bangalore.
9 Q. Okay. So you said that you
10 left Cipla in about 2003?
11 A. Yes.
12 Q. What caused you -- what
13 caused you to leave Cipla?
14 A. I wanted to expand my role
15 and go to a bigger organization or bigger
16 role -- my two roles.
17 Q. Okay. Where did you go to
18 after that?
19 A. So I came to a company
20 called Dr. Reddy's in Hyderabad.
21 Q. Okay. And what was your
22 initial position there in 2003?
23 A. I was responsible for head
24 of quality control for all the

<p style="text-align: right;">Page 26</p> <p>1 formulation facilities. There are 2 multiple facilities. 3 Q. How long were you at 4 Dr. Reddy's in total? 5 A. Five years. 6 Q. Was your -- for those five 7 years, was your role the same? Were you 8 head of quality control for formulation 9 the entire time? 10 A. For -- yeah. For all the 11 facilities, yes. That was the role, 12 yeah. 13 Q. When you say all facilities, 14 does that include API and finished dose? 15 A. It was only OSD. It was 16 only OSD. 17 Q. Okay. What does OSD stand 18 for? 19 A. Oral solid dosage forms and 20 injectables. 21 Q. That would include both API 22 and finished dose for OSDs? 23 A. No. In Dr. Reddy's it was 24 only dosage forms. In Cipla it was both</p>	<p style="text-align: right;">Page 28</p> <p>1 there from 2008, roughly? 2 A. Yes. 2008 to 2011. 3 Q. Okay. I have not heard of 4 Shasun before. Is that still an existing 5 company or no? 6 A. The name is changed now I 7 think. But Shasun used to be one of the 8 largest manufacturers of ibuprofen in the 9 world. Yeah. 10 Q. Okay. Were they really just 11 an over-the-counter drug manufacturer or 12 did they do prescription drugs as well? 13 A. They were manufacturing 14 over-the-counter -- I'm sorry, not 15 over-the-counter. Generics, both API and 16 finished dosage forms. 17 Q. And during this time you 18 were also getting your Ph.D.? 19 A. That's right. I was -- 20 before that I had a master's degree. 21 So -- and you know, bachelor degree. So 22 I took Ph.D. 23 Q. Okay. Was your master's 24 degree also in analytical chemistry?</p>
<p style="text-align: right;">Page 27</p> <p>1 API and, you know, dosage forms. 2 Q. Okay. Was Dr. Reddy's not 3 an API manufacturer? 4 A. Yes. But it was a different 5 division. 6 Q. Okay. Understood. So your 7 time at Dr. Reddy's between 2003 and 8 2008, you had only dealt with finished 9 dose manufacturing? 10 A. Yes. 11 Q. Okay. And then what caused 12 you to leave Dr. Reddy's in 2008? 13 A. I wanted to take a bigger 14 role so I moved to a company as head of 15 quality. 16 Q. Which company was that? 17 A. It is a company called 18 Shasun. 19 Q. Could you spell that for me? 20 A. S-H-A-S-U-N, Shasun. 21 Pharmaceuticals. S-H-A-S-U-N. 22 Q. Okay. S-H-A-S-U-N? 23 A. Yes. 24 Q. Shasun. Okay. And you were</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Yes. 2 Q. From the same university? 3 A. No, it is a different 4 university. I will send you all the 5 details in that so I don't misspell my 6 initials. 7 Q. Okay. All right. Sounds 8 good. 9 A. Yeah. 10 Q. So what happened to Shasun? 11 Are they still around? 12 A. They are still around. But 13 they got bought by somebody -- someone 14 else recently, about two years back. And 15 they have become a slightly bigger 16 company now. 17 Q. Okay. What was your role at 18 Shasun? 19 A. Shasun, I was head of 20 quality and regulatory affairs. 21 Q. So oversight of both quality 22 assurance and quality control? 23 A. That's right, yes. 24 Q. And regulatory affairs?</p>

<p style="text-align: right;">Page 30</p> <p>1 A. That's right.</p> <p>2 Q. Did Shasun have any approved</p> <p>3 ANDAs in the United States?</p> <p>4 A. Yes. They had, if my memory</p> <p>5 serves me well, they had their own, as</p> <p>6 well as they were also contract</p> <p>7 manufacturing for some of the customers.</p> <p>8 Q. As an API contract</p> <p>9 manufacturer?</p> <p>10 A. Both. They had that space,</p> <p>11 they were working that space for both API</p> <p>12 as well as solid dosage forms.</p> <p>13 Q. Did you interact with the</p> <p>14 FDA as part of your role as head of</p> <p>15 regulatory affairs at Shasun?</p> <p>16 A. As -- mostly as a quality</p> <p>17 head, because during inspections, it was</p> <p>18 mostly as a functional head for quality.</p> <p>19 Q. What caused you to leave</p> <p>20 Shasun in 2011?</p> <p>21 A. I was actually away from the</p> <p>22 town where my family was, in Hyderabad.</p> <p>23 My family is from Hyderabad. For Shasun</p> <p>24 I had to go to the city, 600,</p>	<p style="text-align: right;">Page 32</p> <p>1 quality oversight from Mylan standpoint.</p> <p>2 Q. When you say third-party</p> <p>3 manufacturing, are you referring to</p> <p>4 like --</p> <p>5 A. Non-Mylan -- non-Mylan</p> <p>6 facilities.</p> <p>7 Q. Okay. Manufacturing what</p> <p>8 exactly?</p> <p>9 A. Dosage forms.</p> <p>10 Q. API or finished dose forms?</p> <p>11 A. No. It was for -- it was</p> <p>12 for -- sorry. It was for formulations.</p> <p>13 Q. Okay. What is the</p> <p>14 difference between -- what do you mean by</p> <p>15 formulations?</p> <p>16 A. It has got all types of</p> <p>17 formulations like creams, ointments,</p> <p>18 injectables, you know, tablets. So</p> <p>19 that's why I did not say OSD. I said</p> <p>20 different types of formulations for</p> <p>21 different markets.</p> <p>22 Q. And those could be in their</p> <p>23 finished state, you know, ready-to-sell</p> <p>24 form?</p>
<p style="text-align: right;">Page 31</p> <p>1 700 kilometers away from Hyderabad from</p> <p>2 there. And that's why I look for</p> <p>3 opportunities in Hyderabad to come back</p> <p>4 to home.</p> <p>5 Q. Okay. What city was Shasun</p> <p>6 in?</p> <p>7 A. Shasun was in Pondichery.</p> <p>8 It is south of a city called Chennai.</p> <p>9 Called -- previously it's called Madras.</p> <p>10 Q. And then did you join Mylan</p> <p>11 next in 2011?</p> <p>12 A. That's right, sir.</p> <p>13 Q. Since 2011, you've always</p> <p>14 worked out of Mylan's corporate office in</p> <p>15 Hyderabad?</p> <p>16 A. That's right.</p> <p>17 Q. What was your role when you</p> <p>18 first joined Mylan?</p> <p>19 A. Yeah, Mylan in 2011 when I</p> <p>20 joined, I joined as head of quality for</p> <p>21 third-party manufacturing in India</p> <p>22 region. So we had products that are</p> <p>23 manufactured by third-party</p> <p>24 manufacturers. So I was providing</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Yeah, that's right.</p> <p>2 Q. How long were you head of</p> <p>3 quality for third-party manufacturing?</p> <p>4 A. I think until early 2004.</p> <p>5 Q. 2014?</p> <p>6 A. I'm sorry, 2014.</p> <p>7 Q. Okay. And then in 2014,</p> <p>8 what role did you move to?</p> <p>9 A. I took the role of head of</p> <p>10 quality for APIs.</p> <p>11 Q. Is that the role that you</p> <p>12 are still in currently?</p> <p>13 A. No. There is an enhancement</p> <p>14 in the role.</p> <p>15 Q. Okay. What is that?</p> <p>16 A. Yeah, after that I also was</p> <p>17 provided additional responsibility of</p> <p>18 India OSD. That is Indian solid oral</p> <p>19 dosage form facilities, quality</p> <p>20 oversight, somewhere in 2016 --</p> <p>21 Q. Okay.</p> <p>22 A. -- as a national role.</p> <p>23 Q. Okay. And so you said that</p> <p>24 was India OSD --</p>

<p style="text-align: right;">Page 34</p> <p>1 A. Correct.</p> <p>2 Q. -- for Indian facilities?</p> <p>3 A. That's correct. Finished</p> <p>4 dose and API.</p> <p>5 Q. Was there -- did that</p> <p>6 include the U.S. market or was that</p> <p>7 solely the India market?</p> <p>8 A. No, this is for the</p> <p>9 manufacturing site that is situated in</p> <p>10 India, but serving all the markets across</p> <p>11 the world.</p> <p>12 Q. Understood. So essentially</p> <p>13 the difference between your 2014 head of</p> <p>14 quality for API role, and in 2016, the</p> <p>15 increased responsibility included, for</p> <p>16 example, finished dose facilities like</p> <p>17 Nashik or Aurangabad?</p> <p>18 A. Yeah. In somewhere in end</p> <p>19 of 2018, I got additional responsibility</p> <p>20 of global OSD.</p> <p>21 Q. That was also in 2016?</p> <p>22 A. No, 2018 or somewhere in '19</p> <p>23 beginning. I don't exactly recollect.</p> <p>24 That's the role that I'm currently in.</p>	<p style="text-align: right;">Page 36</p> <p>1 A. The role -- go ahead.</p> <p>2 Q. Is there a person who is</p> <p>3 now head -- overseeing API quality that</p> <p>4 reports to you now that you have</p> <p>5 increased responsibilities?</p> <p>6 A. We have cluster for sites.</p> <p>7 So there are two cluster heads who</p> <p>8 reporting to me.</p> <p>9 Q. Okay. Who would be the</p> <p>10 cluster head for Unit 8 that reports to</p> <p>11 you for API quality?</p> <p>12 A. Currently it is a gentleman</p> <p>13 called Samba Siva Rao. Samba.</p> <p>14 Q. Okay. How do you spell that</p> <p>15 name?</p> <p>16 A. S-A-M-B-A. S-A-M -- B for</p> <p>17 Bombay. Samba. S for -- I'm sorry.</p> <p>18 Q. Okay. And is that his first</p> <p>19 name or last name?</p> <p>20 A. Yeah, it's the first name.</p> <p>21 Samba.</p> <p>22 Q. Okay. And I think you said</p> <p>23 another name as well.</p> <p>24 A. Other name is Rao. R-A-O.</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Okay. And what is the title</p> <p>2 for that role exactly?</p> <p>3 A. That role -- currently the</p> <p>4 role's title is head of global quality</p> <p>5 for OSD and APIs.</p> <p>6 Q. Who do you report to</p> <p>7 currently?</p> <p>8 A. I report to Derek Glover.</p> <p>9 Q. Have you reported to Derek</p> <p>10 Glover since 2018 or at some point before</p> <p>11 that?</p> <p>12 A. I exactly don't recollect.</p> <p>13 It could be somewhere in that time.</p> <p>14 Q. Okay. When you were head of</p> <p>15 India OSD in 2016, who did you report to?</p> <p>16 A. I reported to -- I reported</p> <p>17 to Reem Malki. She was head of</p> <p>18 operations quality at that time.</p> <p>19 Q. Who took over for the head</p> <p>20 of quality for API role when you moved to</p> <p>21 India OSD?</p> <p>22 A. As I said, it was an</p> <p>23 additional responsibility.</p> <p>24 Q. Okay. Is there --</p>	<p style="text-align: right;">Page 37</p> <p>1 Rao. That's the surname.</p> <p>2 Q. And Samba Rao has been the</p> <p>3 cluster head for API quality at Unit 8</p> <p>4 since when?</p> <p>5 A. I think he is from 2019.</p> <p>6 Q. Who was in that role before</p> <p>7 that?</p> <p>8 A. I think it was -- Srinivasa</p> <p>9 Rao before that. Srinivasa Rao.</p> <p>10 S-R-I-N-I-V-A-S-A, Rao.</p> <p>11 Q. Okay. Who is responsible</p> <p>12 for -- and it might be these cluster</p> <p>13 heads for API quality. But is there</p> <p>14 someone who's responsible for raw</p> <p>15 material vendors?</p> <p>16 A. Raw material vendors?</p> <p>17 There is -- there is a group, a group of</p> <p>18 people who work on quality oversight for</p> <p>19 raw material vendor, and that gentleman</p> <p>20 reported in to me.</p> <p>21 Q. Okay. Who is that</p> <p>22 gentleman?</p> <p>23 A. That gentleman's name was</p> <p>24 Narendar Reddy, N-A-R-E-N-D-A-R, and the</p>

<p>Page 38</p> <p>1 surname is Reddy, R-E-D-D-Y. Narendar 2 Reddy. 3 Q. What was his title? 4 A. He was head of -- head of 5 quality for -- let me think exactly -- 6 for supply -- for supplier, you know, 7 audits. His title is something like 8 that, that he is overall responsible for 9 supplier audits and qualification. 10 Q. Are you familiar with an 11 individual named Vasireddy who was 12 responsible in some way for vendors? 13 A. Yes. He was from the 14 commercial and operations site. 15 Q. What was his title? 16 A. I don't exactly remember 17 what his title was. But I know he was -- 18 he was once upon a time also responsible 19 for managing, you know, supplies from our 20 commercial and operations standpoint. 21 Q. Let's talk about your 22 preparation a little bit today. There 23 might be some questions that I ask you to 24 answer with just a yes or a no. I'm not</p> <p>Page 39</p> <p>1 looking to get into the substance of any 2 of your communications with any lawyers. 3 So -- and I'll let you know when I ask a 4 question like that, that I'm just looking 5 for a yes or a no. 6 So about how many hours did 7 you spend preparing for today's 8 deposition? 9 A. I have not counted. Maybe a 10 couple -- I don't know how to say that. 11 A few hours, for sure. 12 Q. Okay. Over one day or 13 multiple days? 14 A. Maybe a week, ten days, over 15 a period of time, yes. 16 Q. Okay. Who were the lawyers 17 that you met with either in person or 18 virtually to prepare for today? 19 A. I have virtually met Brad 20 from our team, and Mr. Clem and Jason. 21 Q. Okay. Anyone else? 22 A. I don't recollect anyone 23 else. 24 Q. What was the longest one of</p>	<p>Page 40</p> <p>1 those meetings? How long -- for -- you 2 know, you said that you spent several 3 hours over about ten days preparing. Was 4 there a day where, you know, you spent a 5 substantial chunk of the day preparing 6 for this? 7 A. The longest could be like 8 two hours maybe. Two, two and a half 9 hours, I don't know. 10 Q. Did you review documents in 11 preparing for today? 12 A. Some exhibits that were 13 given to me I have reviewed. And there 14 were some other documents which I just 15 scanned through some of them. 16 Q. Sorry, Dr. Gomas. You got a 17 little choppy there. Could you repeat 18 that. 19 A. I'm sorry. Your voice came 20 a little later than the video. Sorry 21 about that. Could you repeat your 22 question once again? 23 Q. I think we had a bad 24 connection there for a second.</p> <p>Page 41</p> <p>1 So, I think you were telling 2 me about documents that you reviewed in 3 preparing for today. 4 A. Yeah, there was -- there was 5 a set of documents that was given to me 6 as exhibits. I did have a look at that. 7 And during the course of our discussion 8 with lawyers, I had an opportunity to see 9 or review some documents, yes. 10 Q. That set of exhibits you're 11 referring to, when did you review that? 12 A. I'm sorry, sir. Which one? 13 Q. You said the set of 14 exhibits. When did you review that? 15 A. The exhibits came the day 16 before yesterday, I think. So it come 17 the day before yesterday or yesterday. I 18 don't recollect. Somewhere in between 19 the timeline, yeah. 20 Q. Okay. Who sent those to 21 you? 22 A. Brad sent them. 23 Q. Do you recall about how many 24 documents that was?</p>
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1 A. Close to 100. 100 or
2 something like that. I don't recollect
3 exact number.
4 Q. Did they have yellow exhibit
5 tabs on them?
6 A. Yeah, one set of documents
7 had -- yes, both yellow -- yellow tag,
8 yes, saying exhibit, yeah.
9 Q. Did all of them have the
10 exhibit tabs or did some of them not have
11 the exhibit tabs on them?
12 A. One set of documents don't
13 have an exhibit tab on that.
14 Q. Okay.
15 A. I have record and I kept.
16 Q. Did you -- aside from those
17 documents, were there documents that you
18 reviewed on your own in preparing for the
19 deposition?
20 A. I did go through some of the
21 guidelines, just to -- you know, and some
22 communications, yeah.
23 Q. Can you tell me specifically
24 what you're referring to?

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1 MR. TRISCHLER: Objection.
2 THE WITNESS: I was looking
3 at the nitrosamine guideline. And
4 a couple of other communications,
5 FDA has put through, to refresh
6 my -- what I was thinking, yeah.
7 BY MR. DAVIS:
8 Q. So the FDA's guidelines on
9 nitrosamines?
10 A. That's right. I just
11 reading through and see.
12 Q. You mentioned communications
13 also. What did you look at there?
14 A. FDA had put a lot of
15 communications out over time about
16 nitrosamines. I had read previously, but
17 I just -- I just, you know, went through
18 it about a couple of vendors just to
19 refresh my memory.
20 Q. Okay. Let's transition a
21 bit and talk about Mylan's root cause
22 investigation into how NDEA and to some
23 extent NDMA got into its valsartan API
24 and finished dose.

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1 Do you know what I'm
2 referring to when I refer to Mylan's root
3 cause investigation?
4 A. I presume that you're
5 talking about nitrosamine impurities.
6 Q. Yes, I am. And so what's
7 your understanding of what that root
8 cause investigation found?
9 A. In the API?
10 Q. Yes.
11 A. Thank you.
12 [REDACTED]

Page 45

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 46

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
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18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 47

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 MR. TRISCHLER: Objection to
20 form. Incomplete hypothetical.
21 You can answer if you can.
22 BY MR. DAVIS:
23 Q. Your answer was yes,
24 Dr. Gomas?

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1 A. I'm sorry. Sorry. Could
2 you re-ask the question? I thought you
3 were asking -- both are being used?
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 Q. What's the difference
21 between organic chemistry and analytical
22 chemistry?
23 A. Analytical chemistry is more
24 on understanding the measurements of, you

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1 know, compounds, and whereas organic
2 chemistry is on the reaction mechanisms
3 and how chemicals interact, et cetera.
4 So there is completely two different, you
5 know, specialization.
6 Q. Okay. And your expertise is
7 more in the analytical realm, not the
8 reaction realm of organic chemistry?
9 A. Analytical measurements and
10 instrumentation, yes.
11 MR. DAVIS: I'm going to
12 mark my first exhibit. This is
13 Tab 23.
14 (Document marked for
15 identification as Exhibit
16 PL-Gomas-1.)
17 MR. DAVIS: I'm going to
18 mark that as Plaintiff Gomas-1.
19 BY MR. DAVIS:
20 Q. Do you -- you said that you
21 had a set of documents, Dr. Gomas.
22 How are those organized for
23 you?
24 A. I have organized by the --

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1 by the serial number.
2 Q. Okay. So is there a serial
3 number that says 23 on it in that stack?
4 A. May I have I look at it,
5 sir.
6 Q. Sure. Absolutely. That's
7 the one that I just marked. I want you
8 to find it so you can look at it with me.
9 A. Thank you. 23, you said,
10 sir?
11 Q. 23, yes. Are you looking at
12 a document that is a two-page document
13 that is two April 23rd, 2020 e-mails?
14 A. No. This is not that
15 document. I'm looking at the Exhibit
16 PL-Glover-23.
17 Q. Okay. That's a different
18 one. What I'll do then is I'll just
19 share my screen. We'll do it that way
20 with this document.
21 A. Okay.
22 Q. Okay. Can you see this?
23 A. Yes, sir.
24 Q. I'm going to -- since I

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1 can't hand over the mouse to you, I'll be
2 your designated scroller.
3 A. Okay.
4 Q. Take a moment to review this
5 and let me know when you're ready to talk
6 about it. It's just a short document.
7 And I'll start with this longer e-mail
8 from Naveen Kumar Kolla. And I'll start
9 with the question, who is Naveen Kumar
10 Kolla?
11 A. Naveen was an employee who
12 was working in the process development,
13 process development laboratory.
14 Q. Okay. Is he a Ph.D.?
15 A. I'm not sure. Sorry.
16 Q. Okay. Do you understand
17 that he's a scientist?
18 A. He's a chemist. Yes.
19 Q. Okay. So do you see that he
20 is sending you and Jyothi Abbineni an
21 e-mail titled "Valsartan - nitrosamine"?
22 A. Yes.
23 Q. Okay. Take a moment to read
24 this, and let me know when you need me to

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1 scroll down further.
2 A. Thank you.
3 MR. TRISCHLER: Dr. Gomas,
4 he just wants you to let him know
5 when you're done reading the
6 e-mail okay.
7 THE WITNESS: Sure, okay.
8 Yes, I just read these two
9 paragraphs.
10 BY MR. DAVIS:
11 Q. Okay.
12 A. Thank you.
13 Q. And there's one more here.
14 A. Yeah, sure. Yes, I finished
15 reading.
16 Q. Okay. I'm going to go up to
17 your e-mail at the top. You forward this
18 e-mail to Walt Owens, Derek Glover and
19 Sanjeev Sethi.
20 Do you see that?
21 A. Yes, sir.
22 Q. You say that it's just for
23 refreshing everyone's memory on specifics
24 of chemistry.

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1 Do you see that?
2 A. Yes.
3 Q. Okay. Is there anything in
4 Dr. Kolla's analysis here that you
5 disagree with?
6 A. It is a description of
7 process chemistry. So in this e-mail,
8 I'm providing a process chemistry of data
9 or what has been presented to me to
10 Dr. Walt. That would have been -- you
11 know, I don't recollect exactly what
12 context it was asked because it is in
13 2020.
14 So but -- it is basically
15 forwarding the chemistry details that has
16 been, you know, shared with me,
17 forwarding it.
18 Q. Okay. There's -- at the
19 time that you forwarded it, you didn't
20 note that you had any disagreement with
21 what Dr. Kolla was saying, correct?
22 A. I don't think it was for me
23 to determine -- have any disagreement or
24 opinion. For me, I think the context

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1 from this e-mail, it appears, you know,
2 that the process chemist, an expert, has
3 provided an explanation, which I'm
4 forwarding to the leadership, Walt Owen,
5 was R&D head at the time, I think.
6 Q. Take a look down -- I'm
7 going to highlight the sentence for you
8 that I want to discuss.
9 A. Sure.
10 Q. Do you see the highlighted
11 sentence?
12 A. Yes, I see that.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 55

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 What is Dr. Kolla saying
16 there?
17 MR. TRISCHLER: Objection to
18 form.
19 THE WITNESS: I cannot
20 really paraphrase what he's
21 saying. I'm just reading what is
22 written, so I have not made any --
23 I cannot understand beyond what is
24 written here.

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1 BY MR. DAVIS:
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: I cannot -- I
16 cannot really, what he -- what
17 context he has written it and what
18 are other limits that need to be
19 considered.
20 So since I'm not the author,
21 I'm not really able to interpret
22 beyond what is written here.
23 BY MR. DAVIS:
24 Q. Well, he sent it to you, did

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1 he not?
2 A. Yeah. I just forwarded that
3 as an information so -- because many
4 times, you know, the senior leadership,
5 they call whoever they want and they ask
6 for information, they don't -- they don't
7 have time to kind of chase each one.
8 So if they send it to me, I
9 will go to individuals and gather that
10 and pass it on to make it a little easier
11 for them. So this is one such
12 information.
13 Q. Did you read the e-mail at
14 the time?
15 A. I cannot really remember
16 that I read it fully. It is too -- it's
17 almost a year back. I get hundreds of
18 e-mails. Unfortunately I won't be able
19 to really say yes or no.
20 Q. When is the last time that
21 you reviewed this e-mail?
22 A. This one?
23 Q. Mm-hmm.
24 A. This e-mail, just now when

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1 you are showing me.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 Q. Yeah.

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1 MR. TRISCHLER: Excuse me,
2 John. Before we leave that
3 document.
4 Is that being identified as
5 Gomas Exhibit 1, that e-mail.
6 MR. DAVIS: Yes. I believe
7 I've marked it. Correct?
8 MR. TRISCHLER: I wasn't
9 sure. That's why I was asking.
10 BY MR. DAVIS:
11 Q. Sure. And, Dr. Gomas, if
12 you wouldn't mind, there's going to be
13 times I might go back to documents. So
14 if you wouldn't mind keeping them in an
15 orderly format.
16 So what I typically advise
17 witnesses to do is to place the first
18 document facedown and then just create a
19 stack, so that, you know, that will be
20 Exhibit 1. It will be on the bottom.
21 And when you flip it back over, it will
22 be on the top.
23 Do you understand?
24 A. Yeah. But this document, I

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1 don't have. So I just --
2 Q. Oh, right. Okay. Sounds
3 good. All right. Well, I'll make a note
4 then that if we go back to this one, I'll
5 just share my screen again.
6 A. Thank you.
7 BY MR. DAVIS:
8 Q. I'm going to mark another
9 one. Let's see if you have this one.
10 You might not, because this was one of
11 the later ones I sent.
12 MR. DAVIS: I'm marking Tab
13 34 as Exhibit 2.
14 (Document marked for
15 identification as Exhibit
16 PL-Gomas-2.)
17 MR. DAVIS: And Tab 35 as
18 Exhibit 3.
19 (Document marked for
20 identification as Exhibit
21 PL-Gomas-3.)
22 BY MR. DAVIS:
23 Q. Do you have those documents,
24 Dr. Gomas, in printed format, or no?

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1 A. Could you please repeat the
2 number, sir. 32 and --
3 Q. 34 and 35. And those would
4 not be -- not be previously marked
5 exhibits. Those -- for ones that were
6 not marked I had a tab number on the file
7 name.
8 So I'm not sure if those
9 were reflected in what was printed for
10 you or not.
11 MR. TRISCHLER: Maybe I can
12 help. Dr. Gomas and Savitha,
13 Frank Stoy from my office sent you
14 those documents in an e-mail at
15 4:57 a.m. my time which would be
16 about 2:27 your time, a few
17 minutes before the deposition
18 began.
19 So I don't know if there's
20 a -- that's where you'll find
21 those documents. I don't know if
22 that's --
23 MR. DAVIS: Should we --
24 we've been going for about an

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<p>1 hour. Should we take a ten-minute 2 break and have those documents 3 printed? 4 MR. TRISCHLER: I think that 5 might make sense, John. 6 MR. DAVIS: Okay. 7 MR. TRISCHLER: We'll be 8 able to find those. 9 MR. DAVIS: Let's go off the 10 record. 11 THE VIDEOGRAPHER: Off the 12 record. 3:25 p.m. 13 (Short break.) 14 THE VIDEOGRAPHER: We are 15 back on the record at 3:46 p.m. 16 BY MR. DAVIS: 17 Q. Okay. Dr. Gomas, we left 18 off, I had just marked Tabs 34 and 35 as 19 Exhibits 2 and 3. 20 I'm going to pull up Tab 34 21 and share my screen with you. I'm going 22 to give you the control. Take a moment 23 to review that e-mail chain, two-page 24 e-mail chain, and let me know when you're</p>	<p>1 sartans and other drugs, and I asked her 2 to take a quick look at the first item. 3 She's been quite busy." 4 Do you see that? 5 A. I read it now. Yes, sir. 6 Q. Okay. And then do you 7 see -- 8 A. I'm sorry. 9 Q. I'm sorry. 10 A. I need to put my credentials 11 into my laptop, because it stopped. I'm 12 sorry to interrupt. Can I do that? 13 Q. Sure. Sure. Let's -- how 14 long will that take? 15 A. Just one second. 16 (Whereupon, a discussion was 17 held off the stenographic record.) 18 BY MR. DAVIS: 19 Q. Do you see on November 25, 20 2019, two days after Frances Zipp e-mail, 21 that you are sending back a few comments? 22 Do you see that? 23 A. I see what I've written, 24 yes, sir.</p>
Page 63	Page 65
<p>1 ready to discuss it. 2 A. Okay. I read through. 3 Q. Okay. So do you recognize 4 the name Lachman Consultants? 5 A. Yes, sir. 6 Q. Who are they? 7 A. They are GMP consultants 8 that the -- they are GMP consultants, 9 yes. 10 Q. And Mylan had retained them 11 to consult on the nitrosamine issue with 12 valsartan? 13 A. As far as my knowledge was, 14 Lachman Consultants are used by the 15 industry for, you know, sometimes 16 responses and for any audit, you know, 17 responses, et cetera. 18 So this was regarding the 19 warning letter response. I think we were 20 consulting them to help us, review it. 21 Q. Okay. Do you see -- do you 22 see that someone named Frances Zipp at 23 Lachman says, "We have a person on our 24 team who is an expert in nitrosamine in</p>	<p>1 Q. You see there's an 2 attachment, "WL Mylan comments by Aloka 3 003 edit 23 November.docx"? 4 A. Yes. 5 Q. Okay. Is Aloka the person 6 that Frances was referring to who is the 7 expert on nitrosamines in sartans? 8 A. I really don't recollect now 9 if it is same person or if it is somebody 10 who had sent the e-mail and that is where 11 the name comes. I'm sorry. I really 12 don't recollect. 13 Q. And there's no one that you 14 know named Aloka at Mylan, is there? 15 A. I don't -- I know -- at 16 least in my -- in my knowledge, there is 17 no one whom I know as Aloka -- 18 Q. Okay. 19 A. -- in Mylan. 20 Q. Okay. I'm going to show you 21 the attachment. This is a pretty lengthy 22 ten-page document. Do you want a few 23 minutes to review it? We can do that, 24 and we can go off the record and you can</p>


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1 take as much time as you want to review
2 it, or I'm really just going to ask you
3 about one portion of it.
4 So what's your preference,
5 Doctor? Or do you want to review the
6 whole thing or do you want to go to the
7 section that I'm going to refer to?
8 A. If you -- if you're going to
9 that section, and if I'm okay to read
10 that section, that would be helpful, sir.
11 Q. Okay. Sure.
12 A. I just -- 34, 35, I have
13 that in front of me too. Just now they
14 brought it.
15 Q. Great. Excellent.
16 Excellent. Okay. So then I'll stop
17 sharing, and I'll direct your attention
18 to Page 2 of this. And I believe you
19 testified that this was -- that Lachman
20 was helping you with audit responses.
21 Does this look to you to be
22 a draft 483 response to the FDA?
23 A. This -- from the title, I
24 understood that it is a warning letter

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1 response, sir.
2 Q. Understood, yeah. Correct.
3 Yeah, yeah. Because of the WL in the
4 title?
5 A. That's right.
6 Q. Okay. So this is a draft
7 Mylan warning letter response, correct?
8 A. Yes, sir. This is a WL
9 response.
10 Q. Okay. And related to Unit
11 8?
12 A. This is related to Unit 8.
13 Q. Go to Page 2. And you'll
14 see, I suppose Mylan's draft response in
15 gray at the bottom of the page.
16 Do you see that?
17 A. I'm sorry, sir. Which page?
18 Sorry. I missed that one.
19 Q. Page 2 at the bottom.
20 A. Okay. Thanks.
21 Q. And do you see where Mylan's
22 response starts with "Response" at the
23 bottom of the page?
24 A. Yes.

Page 68

1 Q. Okay. Do you see some
2 commenters on the side. There's an AS1
3 and there's an NK2?
4 A. Yes. I can see that. Yes.
5 Q. Okay. Do you think NK is
6 Naveen Kumar Kolla?
7 A. I really cannot say that,
8 what the abbreviation was used here.
9 Q. Okay. Do you think AS1 is
10 Aloka at Lachman?
11 A. From the comment, it looks
12 like maybe this is a consultant was
13 commenting, yeah.
14 Q. Okay. So you'll see the
15 first -- the first sentence of Mylan's
16 draft response, and I'll read it because
17 it is a little bit grayed out.
18 

Page 69

1 Do you see that?
2 A. I read that, yes.
3 Q. Okay. Mylan drafted that,
4 correct, that sentence?
5 A. I can't make whether --
6 because it is grayed out.
7 Q. Do you recall that sentence
8 making it into Mylan's final response to
9 the warning letter?
10 A. Until I see, because it a
11 lengthy warning letter response. So I
12 don't recollect any specific element.
13 Q. You see it's a draft here,
14 correct?
15 A. It's here, but I do not know
16 whether it is commented upon or it's
17 really --
18 Q. Sure. Do you see how
19 it's -- that sentence is highlighted
20 compared to the rest of the paragraph?
21 A. Yes.
22 Q. Okay. And do you see a line
23 that goes up to the very top comment from
24 AS1?

Page 70

1 A. Okay.

2 Q. Okay. So that comment from

3 AS1 relates to that sentence?

4 A. Okay. Yeah, so what's the

5 question, sir?

6 [REDACTED]

22 MR. TRISCHLER: Objection to

23 form and foundation.

24 You can answer, if you know.

Page 71

1 THE WITNESS: I'm sorry.

2 Sorry. I missed that one.

3 MR. TRISCHLER: I said

4 objection to form and foundation.

5 BY MR. DAVIS:

6 Q. And you can answer the

7 question.

8 A. I think I really don't

9 recollect this comment, but from what I

10 understood from our investigation, the

11 formation it is not in the downstream

12 because we have already -- you know, as

13 we have seen that, you know, previously

14 in our investigation report.

15 [REDACTED]

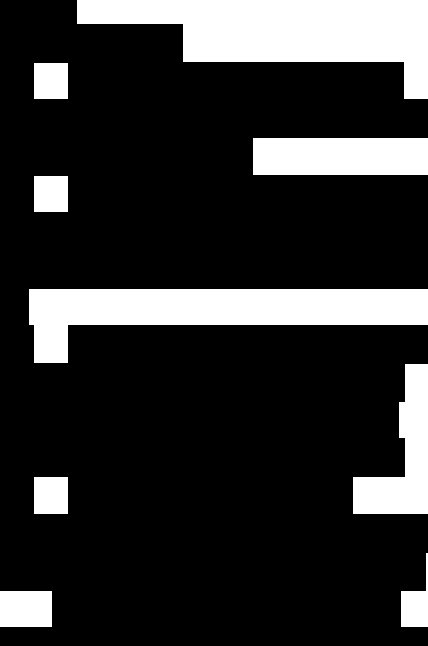
Page 72

1 [REDACTED]

Page 73

1 [REDACTED]

[illegible]



Page 82

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 MR. TRISCHLER: Objection
7 to -- objection to form.
8 The witness doesn't speak
9 for Mylan.
10 Objection, asked and
11 answered.
12 BY MR. DAVIS:
13 Q. Did you draft --
14 MR. TRISCHLER: He's giving
15 you his opinion, John, on it.
16 BY MR. DAVIS:
17 Q. Did you assist in drafting
18 this, Dr. Gomas?
19 A. I was -- I was part of it,
20 but maybe -- but not in all sections, and
21 because there were multiple, you know,
22 leadership, like more too. So I do not
23 know how much I can recollect which part
24 of it was kind of done by me and it's --

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1 but I can generally understand it, but
2 not specifically a comment on this
3 section, what was finally -- you know,
4 how it is this test, sorry.
5 Q. Okay. Yes or no, Dr. Gomas,
6 do you see a reference in this sentence
7 to Mylan's valsartan products, in this
8 one sentence?
9 A. I saw -- yeah, it is -- it
10 is written --
11 Q. Dr. Gomas, let me cut you
12 off. I'm just looking for a simple yes
13 or no answer.
14 Is -- does this sentence
15 anywhere in it refer specifically to
16 Mylan's valsartan product?
17 MR. TRISCHLER: Objection.
18 Objection to form. Argumentative.
19 The witness can answer the
20 question as he deems appropriate.
21 It's not proper to instruct the
22 witness on how to answer a
23 question.
24 MR. DAVIS: I'm entitled --

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1 look, I'm entitled to an answer to
2 my question. It's a simple
3 question. Yes or no, is there a
4 reference in this sentence to
5 Mylan's valsartan.
6 MR. TRISCHLER: He's
7 answered -- John, he's answered
8 the question. What you're not --
9 what you're not entitled to is to
10 instruct him on how to answer.
11 BY MR. DAVIS:
12 Q. You can answer the question
13 again, Dr. Gomas. Is there a reference
14 in this sentence specifically to Mylan's
15 valsartan?
16 [REDACTED]

Page 85

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 86

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 87

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 88

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q. Thank you.

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 89

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 Q. Let's take a look at

16 Plaintiffs' Snider 9.

17 A. Yes, sir.

18 (Previously marked

19 PL-Snider-9.)

20 THE WITNESS: Can I open the

21 file?

22 BY MR. DAVIS:

23 Q. You may.

24 A. Thank you.

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1 Q. Actually before we move onto
2 that, do you -- do you agree, and this is
3 just a very simple pro forma question.
4 For Exhibit 2, do you agree
5 that you did forward that e-mail on
6 November 25, 2019, with comments?
7 Do you want to go back and
8 look at it?
9 A. The name what you showed me,
10 that I sent to, what one?
11 Q. Exhibit 2, which is your
12 e-mail to Derek Glover saying, "Dear
13 Derek, we have reviewed this and have a
14 few comments. Thank you for sharing the
15 inputs from Lachman."
16 You did author -- you
17 authored that e-mail, correct?
18 A. Yes, sir. I did, yes.
19 Q. Okay. Thank you.
20 Back to Plaintiff Snider 9.
21 Do you have that in front of you?
22 A. Yes, sir.
23 Q. Okay. When is the last time
24 you reviewed this e-mail exchange?

Page 91

1 A. This I reviewed it as part
2 of the exhibits when I took -- when I
3 took printouts.
4 Q. So yesterday?
5 A. Yesterday, yeah.
6 Q. Okay. And you did write
7 this e-mail on July 16, 2019 that's the
8 top e-mail?
9 A. Yes, sir.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 92

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 93

1 [REDACTED]
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3 [REDACTED]
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5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
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23 [REDACTED]
24 [REDACTED]

<p>Page 94</p> <p>1 [REDACTED]</p>	<p>Page 96</p> <p>1 [REDACTED]</p>
<p>Page 95</p> <p>1 [REDACTED]</p>	<p>Page 97</p> <p>1 [REDACTED]</p> <p>23 Q. Okay. Did you -- let's</p> <p>24 transition and talk about nitrosamine</p>

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1 testing a little bit, when Mylan started
2 testing its API and finished dose for
3 nitrosamine impurities. Did you
4 spearhead that effort?
5 A. I would -- I would say that
6 yes as a head of quality, I was -- I was
7 overseeing the, you know, the
8 investigation and program for testing.
9 Because we also had to manage a lot of
10 resources, review the new
11 instrumentation.
12 So it is not a normal
13 investigation as you -- as you would have
14 recognized it. So we had to -- we had to
15 mobilize instrumentation. So I was -- I
16 was definitely involved in that, yes.
17 Q. Okay.
18 MR. DAVIS: I'm going to
19 mark Tab 6 as Exhibit 4.
20 (Document marked for
21 identification as Exhibit
22 PL-Gomas-4.)
23 MR. TRISCHLER: That's part
24 of the stack that I think is being

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1 copied, John. So you may have to
2 display that one. I don't think
3 the document is back yet.
4 MR. DAVIS: Okay. Sounds
5 good.
6 BY MR. DAVIS:
7 Q. I'm going to share my
8 screen, Dr. Gomas.
9 A. Yes, sir.
10 Q. Okay. This is -- some of
11 these documents that are produced to us
12 by Mylan come with a slip sheet as the
13 first page so I'm going to scroll past
14 that.
15 And then do you see this
16 e-mail chain around November 15, 2018?
17 A. Yes, sir.
18 Q. Okay. And I'm just going to
19 focus on one thing you say which is on
20 November 14, 2018, you write an e-mail
21 that says, "We are planning to analyze
22 batches, latest to old."
23 Do you see that?
24 A. Yes, sir.

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1 Q. Okay. Is that, in fact,
2 what Mylan did?
3 A. I don't really recollect how
4 finally we tested, whether -- whether all
5 the batches that are within the expiry, I
6 don't recollect, sir. I'm sorry. It's
7 two years back.
8 Q. Let me share another
9 document with you then.
10 MR. DAVIS: I'm going to
11 mark Tab 7 as Exhibit 5, which is
12 an Excel spreadsheet that I'm
13 going to display.
14 (Document marked for
15 identification as Exhibit
16 PL-Gomas-5.)
17 THE WITNESS: Yes, sir.
18 BY MR. DAVIS:
19 Q. Okay. Do you see this,
20 Dr. Gomas?
21 A. Yes, I do see, yes.
22 Q. For the record this is
23 MYLAN-MDL2875-00895544.
24 I'll give you a little

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1 backstory to this. I requested that
2 Mylan produce the latest testing results
3 for nitrosamines that Mylan had done.
4 And this is what counsel provided to me.
5 Did you assist counsel in
6 any way looking for that -- this
7 document?
8 A. This -- I have organized for
9 the site to provide one document that was
10 asked to me about the updated ST list.
11 But I don't know whether it is this or
12 any other document. But I did not see
13 it.
14 Q. Okay. Approximately when
15 did that happen?
16 A. About last week or
17 something.
18 Q. Okay. So I'll represent to
19 you this is the only document with
20 testing results that I received and it
21 corresponds to that timeline. So I
22 believe we're referring to this document.
23 So have you -- do you see
24 that the worksheets at the bottom here,

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1 that I'm scrolling over?

2 A. Yes, sir.

3 Q. Okay. And these refer to

4 the different ANDAs for

5 valsartan-containing products that Mylan

6 has approved for the U.S. market,

7 correct?

8 A. I can see the product name

9 and the batch number.

10 Q. I'm referring simply to the

11 worksheets at the bottom. For example,

12 the one we are on right now, 090483 AML

13 VAL. What does that refer to?

14 A. Oh, I'm so sorry, sir. I'm

15 not able to see that on the screen.

16 Q. Oh. Now can you see it?

17 A. You're talking about the

18 additional Excel sheet files attached to

19 this one?

20 Q. Sure. I'm toggling between

21 some worksheets right now. And do you

22 see what the worksheet title is at the

23 bottom of each?

24 A. I'm sorry. I'm only able to

Page 103

1 see the 41, the Line Item 41. That is

2 43. That is the last item that I see on

3 my screen.

4 Q. Okay. Well, let me just --

5 I'll read it into the record. This

6 worksheet is titled 090483-AML-VAL.

7 Do you see that refers to

8 the ANDA number for amlodipine valsartan?

9 A. Can you please tell me once

10 again? I'm so sorry. Let me hear you

11 once again.

12 Q. Sure. 090483 does that

13 correspond to the ANDA number for Mylan's

14 amlodipine valsartan product?

15 A. I'm so sorry. I'm not very

16 familiar with the ANDA numbers, how the

17 number system is, so sorry about that.

18 Q. Okay. Let's do it this way.

19 Do you see the column here "Description,

20 finished dose form"?

21 A. Yes.

22 Q. Okay. Do you see how it

23 said, "Amlodipine/valsartan tab"?

24 A. Yes.

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1 Q. Okay?

2 A. I can see that.

3 Q. Okay. And for this next

4 worksheet that I've clicked on, do you

5 see how it says, "Valsartan/HCTZ tab"?

6 A. Yes, sir.

7 Q. Okay. And then for this

8 final worksheet, do you see how it just

9 says it's plain valsartan tab?

10 A. Yes.

11 Q. How did you know to find

12 this document when -- when counsel asked

13 you for it?

14 A. I had requested the site

15 quality team to find out, you know,

16 because there were more than, if I

17 recollect, hundreds of batches we tested.

18 So I asked them to find an

19 Excel sheet or document, whatever was

20 made, whether recently or previously or

21 updated. So they have sent this.

22 I really do not know when

23 this was present or they updated it,

24 because it is quite some time before all

Page 105

1 these batches were tested.

2 Q. Mm-hmm. And when you asked

3 the site quality team for this, who -- do

4 you have a name for me?

5 A. I'm sorry?

6 Q. Do you have a name of an

7 individual that you went to at the site

8 quality team to ask this for this?

9 A. Yeah. The quality head of

10 the site, yes. His name is Venkat.

11 Q. Venkat?

12 A. Yes, sir.

13 Q. What's his last name?

14 A. Venkat Bopana, B-O-P-A --

15 B-O-P-A-N-A.

16 Q. Okay. And when you asked

17 him for this, did you ask him for the

18 most recent or the most updated

19 nitrosamine testing results?

20 A. I am really sorry. I am not

21 able to recollect what exactly I asked

22 him.

23 Q. What did you -- what did you

24 ask him for specifically that yielded

Page 106

1 this document?

2 A. I said that, you know, the

3 up-to-date list of testing or something

4 like that. Maybe said -- I really don't

5 recollect what exactly I said.

6 Q. You don't recall asking for

7 the most recent testing?

8 A. I'm sorry. Whether it was

9 that -- no, I don't recollect the dates,

10 sorry. It's about a week back. Exactly

11 what I asked them, I don't recollect.

12 Q. Okay. Do you know if Mylan

13 has tested all of the API batches for

14 valsartan?

15 A. I need to go back and review

16 the documents, but -- but I could

17 definitely say that we have tested close

18 to about 800 API lots if I'm not -- if my

19 memory -- if my memory is right, I mean

20 across all the markets together.

21 Q. Okay. And for -- how many

22 for the U.S. market?

23 A. U.S. market, I think, if my

24 memory serves me well, it is about 160 or

Page 107

1 150. I need to go back and check the

2 documents. But I remember something with

3 that number.

4 Q. Okay. Do you agree --

5 A. The number.

6 Q. Sure. Okay. And do you,

7 and I'm happy to go through this with

8 you. And I can even hand control over of

9 the mouse to you, I believe. So let's

10 see. Okay. I'm going to hand remote

11 control to you, Dr. Gomas.

12 A. Yes, sir.

13 Q. Okay. What I want you to do

14 is -- first of all, do you agree with me

15 that Column K of this particular

16 worksheet refers to the NDEA content in

17 parts per million of the API batches?

18 A. It's very hard to read. One

19 second, sir. Let me read it.

20 Q. You can zoom in if you like

21 or I can zoom in for you.

22 A. I can read now. NDEA

23 content, in bracket, ppm. And I can't

24 read the next line. API, not more than

Page 108

1 0.08 ppm as per FDA guidelines.

2 Is that right, sir?

3 Q. Yes. I think it says as per

4 EU guidelines.

5 A. EU guidelines because --

6 Q. Otherwise -- right.

7 A. The cursor was blocking it.

8 Q. Okay. So what I want you to

9 do is scroll down, and you'll see a bunch

10 of rows that say "yet to be analyzed."

11 Do you see that?

12 A. Yes, sir.

13 Q. Okay. Do you know whether

14 those were tested or not?

15 A. No, I wouldn't be able to

16 answer that question without seeing

17 really the documents.

18 Q. Okay. Regardless, this

19 document was provided to you a week ago

20 by the site quality team?

21 A. It was not provided to me.

22 I asked them to send it to -- send the

23 document. It was not sent to me. It was

24 sent to Brad, I think.

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1 Q. Okay. But that was about a

2 week ago that that request was made?

3 A. Yeah, maybe a week, ten

4 days. It could be something of that

5 sort, yes, sir.

6 Q. Okay. So this document was

7 pulled from the site quality team's file

8 a week ago, is your understanding?

9 A. I could ask them, you know,

10 whether this is an updated one or is the

11 usual one.

12 Q. Why would -- why do you

13 think that they would send you one that's

14 not the most recent version?

15 MR. TRISCHLER: Objection to

16 form.

17 THE WITNESS: I don't know

18 in what context this was asked

19 for. So I really do not

20 understand whether this is a

21 updated one or not.

22 I myself just not able to

23 make out from this, by -- not on

24 analyzed word alone.

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1 I'm sorry. I'm not able to
2 give you -- you know, the wrong
3 thing here, because I'm not
4 familiar with this -- with this
5 particular document, what -- which
6 is presented here, so...
7 BY MR. DAVIS:
8 [REDACTED]

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1 [REDACTED]

Page 112

1 [REDACTED]

Page 113

1 [REDACTED]

Page 114

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
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7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 Let me go up to this
15 comments here. And it's present in all
16 of the worksheets. And I've highlighted
17 it for you. It says, "Product within
18 expiry recalled."
19 Do you see that?
20 A. Yes, yeah.
21 Q. Okay. Is it correct that
22 Mylan only recalled valsartan that had
23 not passed its shelf life?
24 A. I think I need to -- I need

Page 115

1 to refer to documentation, because off
2 the cuff I don't recollect this. It's
3 about three years now, so exactly what
4 was recalled, I'm not able to recollect.
5 Q. Okay. So you don't know for
6 example, and I'll -- I'm going to pick an
7 example from a while back.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 You don't know whether that
16 batch was recalled or whether it was not
17 recalled simply due to the fact that it
18 was expired already?
19 A. I need to -- I need to
20 refer -- you know, refer this to the team
21 that really did the recall, that is the
22 U.S. team that manages it.
23 Q. Okay. Who would I talk
24 to -- who would I talk to about that in

Page 116

1 particular?
2 A. Derek Glover, Mr. Derek
3 Glover could have someone from his team,
4 you know, could definitely give you that
5 answer.
6 Q. Okay. Do you know if Mylan
7 is still testing valsartan API and
8 finished dose for nitrosamine content
9 that was manufactured prior to the
10 recall?
11 A. I -- as my -- my knowledge
12 goes, no, sir. Because we have -- we
13 have done the recall and we moved onto
14 the new process.
15 Q. Okay. Let's talk about --
16 A. I received the printout --
17 sorry, sir -- before you ask the
18 question.
19 Q. Yeah, sure.
20 (Whereupon, a discussion was
21 held off the record.)
22 THE WITNESS: I have all the
23 things printed.
24 BY MR. DAVIS:

Page 117

1 Q. Okay, great. Thank you.
2 Thank you.
3 Let's talk about Mylan's
4 risk assessment activities for its
5 recovered solvent processes that were
6 done prior to the recall.
7 Do you follow the topic I'm
8 going to?
9 A. Yes, sir.
10 Q. Okay. What did Mylan do
11 from a risk assessment perspective for
12 its recovered solvent processes prior to
13 recall in 2018 for valsartan?
14 A. Risk assessment as a
15 specific exercise or risk assessment as a
16 whole? What we -- because risk
17 assessments are performed in multiple
18 ways, you know, across cGMP processes.
19 So we have under product
20 specification design, control of testing,
21 control of process parameters. So all of
22 them we consider a risk assessment.
23 So if you could be more
24 specific, please.

Page 118

1 Q. Sure. Let me make sure I
2 got you right on this.
3 A. Yes, sir.
4 Q. You mentioned three things.
5 You said the specification testing --
6 A. Yes, sir.
7 [REDACTED]

Page 120

[REDACTED]

Page 119

1 [REDACTED]

Page 121

1 [REDACTED]

Page 122

1 [REDACTED]
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16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 123

1 [REDACTED]
2 [REDACTED]
3 Q. Who is the head -- who was
4 the head of R&D, you know, between 2010
5 and 2018?
6 A. Oh, I -- 2010, I don't know.
7 But when I join in 2014, in the API
8 group, there was a gentleman, Dr. -- he
9 left, so I'm not recollecting his name.
10 I really don't know who the
11 people that were previously.
12 Q. Who is the current --
13 A. I can tell you the current
14 name.
15 Q. Who is the current person?
16 A. The current R&D head for the
17 API sections Dr. Chandra Has.
18 Q. Can you spell that for me
19 please?
20 A. Yes, sir. C-H-A-N-D-R-A,
21 H-A-S. Chandra Has.
22 Q. H-A-S?
23 A. Yes, sir. Chandra Has.
24 Q. And that's the head of R&D

Page 124

1 for API?
2 A. For API, yes, sir.
3 Q. Where is Dr. Has based out
4 of?
5 A. He is based out of Hyderabad
6 R&D center.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
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Page 125

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23 [REDACTED]
24 [REDACTED]

Page 128

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Page 129

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[REDACTED]

Page 130

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2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

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9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 MR. DAVIS: Am I getting

24 lost?

Page 131

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 133

1 Hey, Bill, can you hear me

2 okay?

3 THE VIDEOGRAPHER: I can

4 hear you.

5 MR. DAVIS: Okay. Where is

6 the choppiness, is it on my end or

7 the witness's?

8 THE VIDEOGRAPHER: I mean I

9 think it's on the witness's end.

10 I see him freeze for a bit and

11 then the video catches up, but the

12 audio sounds okay. And then it

13 lines up again, so -- it doesn't

14 happen often. But I feel --

15 MR. DAVIS: Okay.

16 THE VIDEOGRAPHER: I feel

17 like the doctor just said

18 something. I didn't hear him.

19 THE WITNESS: So what we

20 could do, sir, we will --

21 THE VIDEOGRAPHER: It's okay

22 now though.

23 THE WITNESS: We will -- we

24 will ask our IT folks during any

Page 134

1 of the breaks when we get if they
2 can look at it and see if anything
3 else they can do.
4 (Whereupon, a discussion was
5 held off the record.)
6 BY MR. DAVIS:
7 Q. Okay. Well, yeah. Let's
8 have you look into that on the next break
9 if there's a -- you know, a better
10 location for example where you might get
11 better signal.
12 A. Yes.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
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19 [REDACTED]
20 [REDACTED]
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23 [REDACTED]
24 [REDACTED]

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13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MR. TRISCHLER: John, we've
19 been going for about an hour and a
20 half so I'd like to give the
21 witness a break.
22 MR. DAVIS: Okay, sure.
23 Yeah, we can take a break right
24 now.

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1 What time do you want to --
2 you want to do ten minutes? We
3 can go off the record.
4 MR. TRISCHLER: Yeah, just
5 five or ten minutes so he can
6 stretch his legs, get a cup of
7 coffee or whatever, but --
8 MR. DAVIS: Okay. Ten
9 minutes sounds good.
10 THE VIDEOGRAPHER: Off
11 video, 5:08 p.m.
12 (Short break.)
13 THE VIDEOGRAPHER: We are
14 back on the record at 5:21 p.m.
15 BY MR. DAVIS:
16 Q. Okay. Just to refresh our
17 memory of what we were talking about,
18 Dr. Gomas.
19 We -- we had discussed the
20 testing that goes into creating a
21 specification for recovered solvents and
22 the process parameters that are looked at
23 when doing risk evaluation, and you
24 referred me over to R&D for that stuff,

Page 138

1 correct?
2 A. Yes, sir.
3 [REDACTED]

Page 140

1 [REDACTED]

Page 139

1 [REDACTED]

Page 141

1 [REDACTED]

Page 142

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

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9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

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14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 Q. Can I ask you to open your

21 binder and pull out Plaintiff Glover-30

22 and Plaintiff Glover-31.

23 A. Sure, sir. 30 and 31,

24 right, sir?

Page 146

1 Q. Plaintiff Glover 030, and
2 031.
3 A. Yes, sir. I do have in
4 front of me.
5 (Previously marked
6 PL-Glover-30.)
7 (Previously marked
8 PL-Glover-31.)
9 BY MR. DAVIS:
10 Q. Okay. So if you look at
11 Plaintiff Glover-30 which is the e-mail,
12 do you see that you are -- it's two
13 e-mails from you, the first e-mail on
14 March 20th, 2019?
15 That was several months
16 after the recall, correct?
17 A. I'm looking at the e-mail,
18 so that we are looking at the same
19 document. I'm looking at the e-mail that
20 was sent by me on 20th of March 2019,
21 sir.
22 Q. Yes. And do you agree that
23 that's several months after the recall?
24 A. Yes, it's a couple of

Page 147

1 months, three months maybe, three,
2 four months after recall, yes, sir.
3 Q. Okay. And Mylan had done
4 its root cause investigation by this
5 point, correct?
6 A. Yes, we have done the
7 investigation report and provided to --
8 provided, yes.
9 Q. Okay. So your -- the
10 subject of your first e-mail is "Backup
11 for FDA call."
12 Do you see that?
13 A. Yes, sir.
14 Q. And then you're e-mailing it
15 to Dr. Walt Owens, and you're saying,
16 "Kindly see the attachment."
17 Do you see that?
18 A. That's right, sir.
19 Q. Okay. And then if you go to
20 the top e-mail, you'll see an attachment
21 that says Valsartan FDA.docx.
22 Do you see that?
23 A. The attachment print starts
24 with date of investigation of Lantech.

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1 And that is the Exhibit 31, sir.
2 Q. Yes. Do you recognize this
3 document?
4 A. Let me have a look at it.
5 Yeah, it's -- it's some
6 questions from Dr. Walt, yes, sir.
7 Q. Okay. Well, it's a -- the
8 title of the document, as you can see
9 from Plaintiff Glover-30, the top e-mail
10 is "Valsartan - FDA.docx."
11 Do you see that?
12 A. On the e-mail, I can see in
13 the subject, but on the exhibit it only
14 say PL-Glover-30 and Exhibit
15 PL-Glover-31.
16 Q. Look at the top e-mail on
17 Exhibit 30, also from you, dated
18 March 20th, 2019, at 10:13 a.m.
19 Do you see that?
20 A. Yes, sir.
21 Q. Okay. And do you see
22 underneath "Subject: FW: Backup for FDA
23 call" an attachment, "Valsartan - FDA"?
24 A. Oh, yeah, I'm sorry. I see

Page 149

1 that now, yes, sir. Sorry.
2 Q. Yeah. Does that remind you
3 that Plaintiff Glover-31, the attachment
4 was backup for an FDA call that Mylan was
5 going to have?
6 A. I believe so, sir.
7 Q. Okay. Did you assist in
8 drafting Plaintiff Glover-31?
9 A. Let me -- it is sent from
10 my, you know, mail. So I'm just reading
11 it. Yes, I have read it. Can I answer
12 now?
13 Q. Okay. Sure. You can
14 answer.
15 A. Yes, sir. So there is --
16 the context here is that Dr. Walt, I
17 remember that maybe he said that he was
18 supposed to have call with FDA. I don't
19 exactly remember the details of call.
20 But it was for a call, so
21 before the call he was asking a few
22 information. So I have gathered this
23 information, either by phone or mail. I
24 don't recollect how it is. But it looks

Page 150

1 like a summary of all the questions, what
2 he asked for, has been gathered and sent
3 from my mail.
4 Q. Okay. Thank you. When is
5 the last time that you reviewed this
6 document?
7 A. This one, when I got the,
8 you know -- for the printouts, when I
9 took the exhibits, I did have an
10 opportunity.
11 Q. Okay. And that was
12 yesterday?
13 A. It was -- from the -- I also
14 had an opportunity to go through the --
15 Mr. Glover's, you know, information, so
16 that maybe I would have seen too. I
17 don't recollect.
18 Q. Did you read the deposition
19 transcript for Mr. Glover?
20 A. A little bit of them, sir,
21 yes.
22 Q. Okay. How about Dr. Snider?
23 A. I didn't get an opportunity
24 to read it, sir. I didn't read it.

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1 Q. Okay. Take a look --
2 MR. TRISCHLER: Yeah, all
3 the -- all the work that we do is
4 of no interest to anybody, John.
5 MR. DAVIS: I'm shocked.
6 BY MR. DAVIS:
7 Q. So take a look down at the
8 last item on Page 2, Dr. Gomas.
9 A. Yes, sir.
10 Q. It asks, "Were they removed
11 from our DMFs if they were ever
12 included?"
13 Do you see that?
14 A. I can read it, yes.
15 Q. Okay. And "DMF" refers to
16 drug master file?
17 A. Yes, sir.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 152

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Page 162

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16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 Q. Okay. I'm going to mark Tab
24 3 as Exhibit 6.

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1 (Document marked for
2 identification as Exhibit
3 PL-Gomas-6.)
4 MR. TRISCHLER: Dr. Gomas,
5 did you get copies yet of the
6 materials?
7 THE WITNESS: I got all
8 the -- I got all the copies, sir.
9 MR. DAVIS: Okay.
10 BY MR. DAVIS:
11 Q. Okay. Can you pull Tab 3
12 out of that binder, Dr. Gomas.
13 MR. DAVIS: Let's go off the
14 record while he locates this.
15 THE VIDEOGRAPHER: Off the
16 record at 5:48 p.m.
17 (Short break.)
18 THE VIDEOGRAPHER: We are
19 back on the record at 5:50 p.m.
20 BY MR. DAVIS:
21 Q. Dr. Gomas, do you recognize
22 this to be two e-mails, both from you to
23 a number of people?
24 A. Kindly give me time to read,

Page 164

1 sir, please. Just a few seconds.
2 Q. Okay. Are you ready to
3 discuss the document, Dr. Gomas?
4 A. One moment, please. Okay.
5 Q. I'm going to focus on the
6 bottom e-mail from you to a number of
7 people. And specifically the last
8 paragraph that's on Page 2 that starts
9 with, "The specification for purity of
10 recovered o-xylene is not less than
11 97 percent."
12 Do you see that?
13 A. Yes, sir.
14 Q. Okay. Do you see the last
15 sentence of this paragraph? It says,
16 "The analytical method is designed for
17 determining the overall purity and not
18 for any specific impurities, such as
19 NDEA."
20 Do you see that?
21 A. I see that.
22 Q. Is what you wrote there
23 accurate?
24 A. This is in November 2018.

Page 165

1 Q. At the time, was what you
2 wrote accurate?
3 A. I think -- I think I need to
4 provide -- because I recollect, you know,
5 understanding this concept, because if
6 you look at the analytical methodologies
7 that are prescribed by every regulatory
8 agencies, as well as the industry, it's
9 extremely sophisticated and sensitive
10 instruments for that nitrosamines
11 impurities because of the levels that are
12 expected. So a conventional GC method is
13 not expected to see such low levels. So
14 from --
15 Q. Before -- before you go on,
16 Dr. Gomas, I'm going to cut you off
17 because you're talking about nitrosamine
18 testing. [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 Do you understand that?
22 MR. TRISCHLER: John, I
23 don't think it's fair to cut the
24 witness off. It's not fair at

Page 166

1 all.
2 MR. DAVIS: I don't think
3 it's fair --
4 MR. TRISCHLER: At the
5 beginning of the deposition, you
6 said that you were not going to do
7 that.
8 MR. DAVIS: I don't think
9 this filibustering is fair either.
10 MR. TRISCHLER: Well, you
11 know, I object to the
12 characterization of filibustering.
13 I think the witness was
14 trying to answer the question.
15 And so I would just appreciate the
16 courtesy of allowing him to do
17 that.
18 BY MR. DAVIS:
19 Q. Okay. Let me ask my
20 question again, Dr. Gomas, just to make
21 it extra clear.
22 [REDACTED]
23 [REDACTED]

Page 167

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22 [REDACTED]
23 [REDACTED]

Page 169

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
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22 [REDACTED]
23 [REDACTED]

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1

1

[REDACTED]

[illegible][illegible]

Page 178

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

Page 180

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 MR. TRISCHLER: Objection.

19 BY MR. DAVIS:

20 Q. Do you want -- do you want

21 to go back to the document and talk about

22 it more now that you're willing to talk

23 about it?

24 MR. TRISCHLER: Well, he

Page 179

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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1 doesn't want to do anything except

2 answer your questions, and I

3 haven't heard one, John. You're

4 just arguing. What's the

5 question?

6 BY MR. DAVIS:

7 Q. Let's take a look at

8 Plaintiff Glover-6 and 7.

9 A. You said 67? Six and seven,

10 sorry.

11 MR. TRISCHLER: Excuse me,

12 John, before we go to that, the

13 e-mail that we were just talking

14 about, I think was --

15 MR. DAVIS: That's

16 Exhibit 6.

17 MR. TRISCHLER: Exhibit 6.

18 Thank you.

19 THE WITNESS: Yes, I have it

20 in front of me, sir.

21 BY MR. DAVIS:

22 Q. Okay. Take a look at

23 Exhibit 6 and the participants to this

24 e-mail chain, all of whom appear to be

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1 Mylan individuals. Mylan.in, is that
2 Mylan Laboratories Limited?
3 A. Yes, sir.
4 Q. Okay. Do you recognize any
5 of these individuals' names?
6 A. I can recognize Venkata
7 Anabathula. That is one person that I
8 can recognize.
9 Q. Okay. He's in the quality
10 assurance department?
11 A. He is -- at that time, I do
12 not know whether he was in QA or QC, but
13 it was at least safe to say he's a
14 quality -- a quality function individual.
15 Q. Okay. How about the author
16 of the e-mail, Sudhakar Reddy?
17 A. I don't know him. I don't
18 know which level because there are
19 hundreds of employees. I'm sorry. I
20 don't know this individual.
21 Q. Okay. Do you see his
22 signature line says that he's in quality
23 assurance at Unit 8?
24 A. It says that he's -- I'm

Page 183

1 sorry. It says that he is from Unit 8
2 quality assurance, but I don't know him
3 personally, so...
4 Q. Okay. But you do -- you
5 recognize Venkata?
6 A. Venkata, yes, I know he's in
7 the quality function.
8 Q. Okay. Do you see that the
9 subject of the e-mail is "Quality risk
10 assessment of usage of recovered solvents
11 in manufacturing of pharmaceutical
12 intermediate API"?
13 A. I do see that, sir.
14 Q. Okay. Do you see there's an
15 attachment there that says, "Usage of
16 recovered solvents in manufacturing of
17 pharmaceutical intermediate API.doc"?
18 A. I do see that.
19 Q. Okay. And then looking at
20 Plaintiff Glover-7, is that a document
21 you reviewed before?
22 A. I would have seen it, but I
23 don't recollect. There are so many
24 attachments. I would have seen it too.

Page 184

1 Q. Okay. You would have seen
2 it in preparing for this deposition or,
3 you know, prior to that?
4 A. I can't recollect. There
5 are so many documents we went through.
6 I'm sorry. I'm not able to recollect.
7 Q. Okay. My question is, at
8 the time this e-mail and attachment was
9 sent on October 17th, 2014, as you see
10 from the e-mail Plaintiff Glover-6, did
11 you have any awareness of this document's
12 existence around that time?
13 A. No, sir. I have not -- no.
14 Q. Okay.
15 A. I don't recollect.
16 Q. But you did look at it at
17 some point as part of preparation for
18 today?
19 A. Yes, sir. Yesterday when we
20 looked into those, I looked at it. Yeah.
21 Q. Do you see from the title of
22 the risk assessment that it says that it
23 relates to the usage of recovered
24 solvents in the manufacturing of

Page 185

1 pharmaceutical intermediate and API?
2 A. Yes. It does say that, sir,
3 yes.
4 Q. And that's in fact what it
5 relates to, correct, this risk
6 assessment?
7 A. I've not gone through the
8 entire document line by line. At least
9 the title say so.
10 Q. Okay. Well, based on your
11 review of it at some point before today,
12 would you agree that the document in fact
13 does relate to the usage of recovered
14 solvents in the manufacturing of
15 pharmaceutical intermediate and API?
16 If you want a few -- if you
17 want a few minutes to review it,
18 Dr. Gomas, we can go off the record and
19 you can do that. Would you like that?
20 A. I would like to see this
21 objective and scope for more time just to
22 read it.
23 MR. DAVIS: Okay. We can go
24 off the record.

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1 THE WITNESS: Yes, sir.
2 Thank you.
3 THE VIDEOGRAPHER: Off the
4 record. 6:14 p.m.
5 (Short break.)
6 THE VIDEOGRAPHER: We are
7 back on the record. 6:14 p.m.
8 BY MR. DAVIS:
9 Q. Okay. Having reviewed the
10 scope and objective of the document,
11 which for the record is on Page 3, do you
12 agree that in fact this risk assessment
13 from October 2014 looks at the usage of
14 recovered solvents in manufacturing of
15 pharmaceutical intermediate and API?
16 A. That's what the scope of the
17 document says, sir.
18 Q. Okay. Thank you. You'll
19 notice on the last page -- or
20 second-to-last page, 12 of 13, that it's
21 unsigned.
22 Do you see that?
23 A. I recognize that, yes, sir.
24 Q. Okay. Is it Mylan's quality

Page 187

1 assurance practice not to sign documents
2 like this or do these routinely get
3 signed once they are completed?
4 A. I really do not know the
5 context of this document, and I have not
6 seen it until it was presented to me as
7 an exhibit. And so it is -- absolutely I
8 don't have any understanding of what the
9 background behind it, and I absolutely
10 have no understanding of this document.
11 Q. Okay. Well, I'm referring
12 more generally to quality assurance
13 documents, since you are the head of
14 global quality for API.
15 And so, you know, and
16 Unit 8, you would agree, is an API
17 manufacturing facility, right?
18 A. Yes.
19 Q. Okay. And this -- you see
20 in the top left corner of the document
21 that it says it's a Unit 8 document?
22 A. That is right.
23 Q. Okay. And then you see in
24 the top right corner of the document, a

Page 188

1 report number that includes QAD in the
2 number.
3 Do you see that?
4 A. It says QAD, yes.
5 Q. And that refers to the
6 quality assurance department at Unit 8?
7 A. I presume, yes, that would
8 be the abbreviation, yes, sir.
9 Q. Okay. And so -- and you
10 have oversight as the global head -- or
11 the head of global quality for API over
12 the quality assurance department at
13 Unit 8, correct?
14 A. Yes, sir.
15 Q. Okay. And is it the
16 practice of the quality assurance
17 department at Unit 8 for reports similar
18 to this -- I'm not talking specifically
19 about this report, but similar reports
20 that are generated that those reports
21 actually be signed when they're finished?
22 A. Any GMP documentation that
23 is finalized and then reviewed and
24 approved would have all the signatures.

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1 Absolutely. Yes.
2 Q. So if this were -- if this
3 were finalized, there should be a signed
4 version of this somewhere?
5 A. If this was finalized, there
6 should have been a signature version,
7 sir.
8 Q. Okay. Based on your review
9 of this document, do you agree that it
10 pertains to recovered solvents generally
11 and not to any particular recovered
12 solvent or particular API?
13 MR. TRISCHLER: Objection to
14 the form.
15 You can answer.
16 THE WITNESS: As I said, I'm
17 just going by the text, what is
18 written, without any context of
19 why it was made.
20 But at least from the text
21 on the title, it seems -- it looks
22 like it is a common approach kind
23 of a thing.
24 BY MR. DAVIS:

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1 Q. Okay. You don't see any
2 reference to any particular recovered
3 solvent anywhere in this document, do
4 you?
5 A. At least whatever quick
6 readthrough I did, I didn't notice
7 anyone -- anything.
8 Q. Okay. You don't see any
9 reference to any particular API product
10 in this document, do you?
11 A. Whatever -- whatever little
12 bit briefly I looked at it, I didn't see
13 anything.
14 Q. Okay. Do you know if
15 Mylan's quality assurance department
16 created any kind of risk assessment
17 similar to this that pertained
18 specifically to valsartan API and the use
19 of recovered solvents?
20 MR. TRISCHLER: At Unit 8 or
21 anywhere, John?
22 MR. DAVIS: At -- well,
23 since it's valsartan API, I'm
24 assuming that I'm limiting the

Page 191

1 question to Unit 8.
2 BY MR. DAVIS:
3 Q. You can answer, Dr. Gomas.
4 A. I'm not aware of any such
5 documentation.
6 Q. Okay. And how about any
7 particular recovered solvents at all
8 regardless of the API for Unit 8?
9 A. Again, I wouldn't be able
10 to, you know, say that because it is a
11 site level documentation. It is not
12 necessary all the documentations of site
13 would come to my purview or review. So I
14 really do not know whether any such
15 documents exist.
16 Q. Okay. Are you personally
17 aware of anyone, whether it's quality
18 assurance or anyone else at Mylan,
19 actually doing a risk assessment for
20 recovered solvents and their use in
21 valsartan API?
22 A. As my memory goes, sir, I
23 cannot recollect any such document, you
24 know, in my -- to have come across.

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1 Q. Okay. As part of its
2 corrective actions taken at Unit 8, as a
3 result of the two FDA inspections in 2018
4 and '19, Mylan did agree to do recovered
5 solvent risk assessments as part of those
6 corrective actions, did it not?
7 A. I need to really
8 specifically look at that section. I
9 won't recollect it by memory, sir.
10 Q. Okay.
11 A. But there are several of
12 that review every one.
13 Q. All right. Let me help you
14 by marking an exhibit or two.
15 A. Yes, sir.
16 MR. DAVIS: All right. This
17 is Tab 18 which is Exhibit 7.
18 (Document marked for
19 identification as Exhibit
20 PL-Gomas-7.)
21 THE WITNESS: If you could
22 tell me the bottom number, sir,
23 that would be extremely helpful.
24 MR. DAVIS: Sure.

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1 And then Tab 19, which would
2 be the one right after it is
3 Exhibit 8. And I'll give you the
4 Bates number right now.
5 THE WITNESS: But only the
6 last three digits if you can,
7 that's fine.
8 MR. DAVIS: Okay.
9 THE WITNESS: Thank you.
10 Sorry about that.
11 MR. DAVIS: Not a problem.
12 (Document marked for
13 identification as Exhibit
14 PL-Gomas-8.)
15 MR. DAVIS: All right. So
16 Tab 18, Exhibit 7, is a one-page
17 e-mail. The last three would be
18 618 of the Bates number.
19 THE WITNESS: Yes, sir, I
20 have it in front of me.
21 BY MR. DAVIS:
22 Q. Okay. And then the document
23 behind that should be roughly a 21-page
24 document that's titled Commitment Status

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1 Periodic Update.
2 Do you see that?
3 A. Yeah, the attachments, at
4 least the first one says USFDA Periodic
5 Update, yes, sir.
6 Q. Okay. Do you want a few
7 minutes to review the attachment or do
8 you want to talk about it?
9 A. I'm sorry. Here, I have
10 these two document. Let me confirm. The
11 other one, the number is 619, sir, at the
12 bottom?
13 Q. That's correct.
14 A. Thank you, sir. I really --
15 Q. Sure, yeah, if you need a
16 few minutes.
17 MR. DAVIS: We can go off
18 the record.
19 THE WITNESS: Thank you.
20 THE VIDEOGRAPHER: Off the
21 record 6:23 p.m.
22 (Short break.)
23 THE VIDEOGRAPHER: We are
24 back on the record at 6:27 p.m.

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1 BY MR. DAVIS:
2 Q. Okay. Looking at Exhibit 7,
3 Dr. Gomas, do you see that that's an
4 e-mail sent on March 25, 2020?
5 A. Yes, sir.
6 Q. Okay. Sent to the FDA?
7 A. That's right.
8 Q. The attachment you'll see
9 referenced in the e-mail says U.S. FDA
10 Periodic Update - Mylan API Unit-8,
11 (FEI#3002785310).pdf. Do you see that?
12 A. Yes.
13 Q. What were these periodic
14 updates that Mylan was providing to the
15 FDA?
16 A. So during our inspection
17 they have forwarded three observations
18 that were issued.
19 Within 15 days there every
20 organization needs to respond with what
21 actions we are initiating, what
22 corrections. And so within 15 days, the
23 organization sent the response to FDA.
24 Because most of the actions probably will

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1 not get completed in 15 days, because
2 it's too short, we sent -- the
3 organization sent periodic update saying
4 what are the actions that have occurred
5 and how it is progressing. So this is
6 one of those documents.
7 Q. Does that continue until
8 the -- the FDA is satisfied with the --
9 the corrective actions?
10 A. There could be -- no. It is
11 two ways to look at it. Sorry. One is
12 this is a way of communication to the FDA
13 how we are progressing on corrective
14 actions.
15 And so -- so, you know, they
16 can -- they can look at it and make a
17 decision that all the corrective actions
18 could be there, some are corrective
19 actions, so they can make an assessment
20 of a site, you know, evaluation based on
21 that. Sometimes it is not necessarily
22 all the corrective actions need to be
23 completed.
24 Q. Okay. Is Mylan still in the

Page 197

1 process of providing periodic updates
2 like this to the FDA for Unit 8?
3 A. If my memory goes right for
4 Unit 8 we have completed the periodic
5 updates, that's what my memory says. I
6 can check, but -- yeah, because it is
7 2018 inspection, 2019 inspection. So I
8 feel that they were completed the
9 periodic updates, unless -- I can --
10 exactly I cannot remember, but we would
11 have -- we would have -- we would have
12 probably completed I think.
13 Q. Okay. When would that
14 have -- when would the last one of these
15 periodic updates have been sent, do you
16 think?
17 A. I'm sorry, very difficult to
18 recollect that. I'm sorry about that. I
19 won't remember that.
20 Q. Okay. Let's look at
21 Exhibit 8, and I'm going to direct your
22 attention to Page 15. There is a
23 numbering at the bottom center.
24 A. Yes, sir.

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1 Q. And you'll see Page 15 of
2 20.
3 A. I'm there, sir.
4 Q. And then you'll see the
5 column that says Commitment, do you see
6 that?
7 A. Yes, sir.
8 Q. That's Mylan's commitment to
9 the FDA, correct?
10 A. I'm sorry, I missed that. I
11 was reading, sorry.
12 Q. Yeah, sure. I am just
13 trying to understand what commitment
14 refers to.
15 And is -- does commitment
16 refer to the commitment Mylan made to the
17 FDA in regards to corrective actions as a
18 result of the inspection of Unit 8 in
19 2019?
20 A. Yeah. These are the
21 commitments from 483 and warning letter
22 combined, and one of this commitment was
23 June 2020. But as I recollect, that
24 action also was completed.


Page 199

1 Q. Okay. And that's -- that's
2 actually my question is, PR -- I'm
3 looking at PR Number 2039727. Do you see
4 that one?
5 A. Yes, sir.
6 Q. Okay. What does -- what
7 does that number refer to?
8 A. This number refers to a
9 record that is -- that is generated in
10 Trackwise, so -- so that -- that it is,
11 you know, it is -- every action, every
12 CAPA corrective action is notified by a
13 number.
14 Q. Okay. So in Trackwise you
15 can go in and plug in that number for
16 example, and pull up all the associated
17 documents that -- that were created by
18 Mylan as part of this particular
19 corrective action?
20 A. Yeah. There could be
21 attachments for those. And so there
22 could be a parent document which says
23 these are the corrections. Then the
24 evidence would be attached or it would be

Page 200

1 kept separated. Or hard copies would be
2 available. Depends on how we do the
3 site's manager. But definitely the
4 status would be available in the PR
5 number, yes, sir.
6 Q. Okay. And direction, at
7 least a direction as to how to locate the
8 associated documents would be in
9 Trackwise?
10 A. Yes, sir. Yes, sir.
11 Q. Okay. Okay. So for this PR
12 Number 2039727, which says, "Execute a
13 risk assessment of our API manufacturing
14 processes, including raw materials,
15 solvents, reagents, catalysts,
16 byproducts, and recovery processes to
17 identify any risk of formation or
18 introduction of other mutagenic
19 impurities."
20 Do you see that?
21 A. Yes, sir.
22 Q. Okay. And it says that the
23 due date is June 2020?
24 A. Yes.

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1 Q. Okay. Was that, in fact,
2 completed?
3 A. If I -- if I recollect by
4 memory, I think it was completed, yeah.
5 Q. Okay. Let's go to the next
6 page. I'm looking at PR Number 2039860.
7 Do you see that?
8 A. Yes.
9 Q. And similar, that would also
10 be in Trackwise?
11 A. Yes, that is the Trackwise,
12 yes.
13 

Page 202

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 Q. Okay. Yeah, I'm not asking
13 you to remember something that you don't
14 remember.
15 A. Sorry.
16 MR. DAVIS: Let me mark --
17 not a problem.
18 Let me mark Tab 22 as
19 Exhibit 9.
20 (Document marked for
21 identification as Exhibit
22 PL-Gomas-9.)
23 MR. DAVIS: And the Bates,
24 last three on that is 272. It's a

Page 203

1 two-page e-mail.
2 MR. TRISCHLER: Hey, John,
3 I'm not seeing that in the first
4 shared file stack, which I think
5 is what Dr. Gomas is probably
6 looking through.
7 MR. DAVIS: Let's go off the
8 record.
9 THE VIDEOGRAPHER: Off the
10 record 6:36 p.m.
11 (Whereupon, a discussion was
12 held off the record.)
13 THE VIDEOGRAPHER: Back on
14 the record at 6:37 p.m.
15 BY MR. DAVIS:
16 Q. Do you recall, Dr. Gomas,
17 receiving, in June 2020, the warning
18 letter for Unit 8 as a result of the
19 June 2019 inspection?
20 A. In 2019 inspection, warning
21 letter, yes, sir.
22 Q. That warning letter was
23 transmitted to Mylan in this June 23,
24 2020 e-mail that's the bottom e-mail on

Page 204

1 the first page?
2 A. Yeah. I guess so, so yes.
3 Q. Okay. And then do you see
4 your e-mail dated August 9, 2020, that's
5 the top e-mail? Do you see where it
6 says, "Warm regards, Antony," there?
7 A. Yeah, that is in the
8 month -- it's in September that made.
9 Q. Oh, okay. Is the date -- so
10 that would be September 8th, 2020, as
11 opposed to August 9th?
12 A. Yeah.
13 Q. Okay. Understood.
14 A. Yeah.
15 Q. Okay. And do you recall
16 writing this e-mail?
17 A. I don't really, but I can
18 read it and have a context if it is
19 necessary. I wouldn't probably remember
20 why I wrote what I wrote. But yeah, this
21 is my name for sure.
22 Q. Do you see where you write,
23 "So the OAI status continues"?
24 A. Yes, sir.

Page 205

1 Q. Okay. OAI refers to
2 official action indicated, does it not?
3 A. That's right.
4 Q. Okay. Meaning that the FDA
5 was not satisfied with Mylan's responses
6 to its 483 and EIR and warning letters
7 for Unit 8?
8 MR. TRISCHLER: Excuse me.
9 Objection to form.
10 You can answer the question,
11 Dr. Gomas, if you're able.
12 THE WITNESS: Yes, sir.
13 Yes, sir.
14 So, sir, can you please
15 repeat the question please once
16 again? Sorry. I missed that.
17 BY MR. DAVIS:
18 Q. Sure. Let me ask, what does
19 OAI mean --
20 A. OAI means --
21 Q. -- in the context of --
22 A. -- official action
23 initiated.
24 Q. Okay. And what does that

Page 206

1 signify when the FDA says that Mylan
2 Unit 8, for example, is OAI?
3 A. It could -- the -- what
4 actions need to be taken is at the
5 prerogative of FDA. In our case, we
6 receive a warning letter, and we continue
7 to manufacture products, and we are
8 allowed to manufacture and distribute
9 product to -- to the U.S. and other
10 countries from Unit 8, because FDA still,
11 you know, identifies that it is not risky
12 to manufacture product in our facility.
13 Q. And is Mylan Unit 8 still
14 under OAI designation by the FDA?
15 A. At this moment in time, yes,
16 sir.
17 Q. Thank you. How about Unit
18 7? Is Unit 7 OAI as well?
19 A. Yes. At this moment, yes.
20 MR. DAVIS: I'm marking Tab
21 16 as Exhibit 10.
22 (Document marked for
23 identification as Exhibit
24 PL-Gomas-10.)

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1 (Whereupon, a discussion was
2 held off the stenographic record.)
3 BY MR. DAVIS:
4 Q. This one, unfortunately,
5 does not have a Bates number at the
6 bottom right corner. But the first page
7 is Mylan Unit 7 warning letter response
8 dated September 11, 2020.
9 It is a 23-page document.
10 A. Yes, sir.
11 Q. Do you have that?
12 A. Unit 8 right, sir.
13 Q. Unit 7 on this one?
14 A. Unit 7 warning letter. Okay
15 I have that.
16 Q. This is Mylan's response, as
17 it says on the first page.
18 Do you see that?
19 A. You are correct, yes, sir.
20 Q. Okay. I only have one thing
21 that I want to point out and ask a
22 question about. So if you go -- or at
23 least right now I do.
24 If you go to the

Page 208

1 second-to-last page, 22 of 23.
2 A. Yes.
3 [REDACTED]

Page 209

1 [REDACTED]

Page 210

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
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24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. Okay.
12 MR. DAVIS: Do you mind if
13 we take a quick break? I need to
14 get some more coffee in me.
15 MR. TRISCHLER: Yeah, that's
16 fine. It's been almost, you know,
17 an hour and 45 minutes since we
18 broke so now's a good time.
19 MR. DAVIS: Let's go off the
20 record.
21 THE VIDEOGRAPHER: 6:47 p.m.
22 (Short break.)
23 THE VIDEOGRAPHER: We are
24 back on the record at 7:04 p.m.

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1 BY MR. DAVIS:
2 Q. Dr. Gomas, earlier we were
3 talking about sort of risk evaluation
4 activities that could be done related to
5 recovered solvent processes. Do you
6 recall that discussion?
7 A. I do, yes, sir.
8 Q. Okay. And is process
9 validation one of those activities?
10 A. Process validation of API?
11 Yes.
12 Q. I'm talking about process
13 validation of the recovered solvent
14 process itself. Is that something that
15 was -- that could be done as part of a
16 risk evaluation regarding the recovered
17 solvent process?
18 A. As I said, the risk
19 evaluation, risk assessment covers
20 several facets of the process.
21 So if -- specifically if
22 you're asking about the recovered solvent
23 one, using recovered solvent in a process
24 in an API where the API is validated with

Page 213

1 that solvent also would be considered as
2 an adequate, you know, accepted factors
3 from a historical standpoint, yes.
4 Q. Okay. My question though
5 is -- relates to process validation for
6 the recovered solvent process in context
7 of it being used in the API, and you had
8 mentioned process parameters as one of
9 the things that can be done from a risk
10 evaluation standpoint.
11 My question is, does process
12 validation fall within what you described
13 as process parameters?
14 A. That is what I'm trying to
15 kind of explain, that when we use
16 recovered solvent in a fine -- in an API
17 process and validate the process of API
18 and determining the quality equivalence
19 of that API, that is the demonstration of
20 sort of repeat of the process for the
21 recovered solvent too.
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

[illegible]

Page 218

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

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23 [REDACTED]

24 [REDACTED]

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6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 BY MR. DAVIS:

18 Q. Do you agree that it's the

19 job of the quality assurance to establish

20 quality not just based on meeting the

21 spec or simply testing, but to actually

22 evaluate the chemistry and the route of

23 synthesis and everything, that that's

24 also part of quality assurance? Do you

Page 221

1 agree?

2 MR. TRISCHLER: Objection to

3 form.

4 THE WITNESS: I think I

5 remember previously, you know,

6 describing the process of

7 specifications and the chemistry

8 that may be behind, you know,

9 those specifications. And that is

10 all in this job.

11 As I said previously also,

12 and I'm reiterating now, that you

13 are right in one aspect that it is

14 not -- you know, it is not the

15 specification alone.

16 There are other GMP aspects;

17 that is, material -- material

18 input specifications, the process

19 validation of the materials, any

20 deviations, investigations.

21 Those are all elements of

22 quality that goes into ensuring

23 the product quality.

24 So, however, but when it

Page 222

1 comes to demonstrating the
2 repeatability of a product's
3 quality through a validation,
4 which is the purpose of a
5 validation, repeatability, we have
6 to -- we have to refer to
7 previously approved and aligned
8 and agreed quality attributes,
9 that is the specification.
10 And as I said, sir, the
11 final API specification, because
12 the APIs are derived from chemical
13 synthesis, the regulatory
14 agencies, as well as guidelines,
15 qualifies or rather allows the
16 impurities that can originate from
17 various routes in three different
18 buckets, organic impurities,
19 inorganic impurities, and
20 solvents, residual solvents.
21 All three of them are part
22 of our specification, has an
23 overall ensuring quality of the
24 product.

Page 223

1 So -- so the validation
2 finally, at the -- at the end has
3 to comply with the preapproved
4 quality attribute of the
5 specification. And that's the
6 true measurement of repeatability
7 of the process.
8 BY MR. DAVIS:
9 [REDACTED]

Page 224

1 [REDACTED]

Page 225

1 [REDACTED]

Page 228

1

[illegible]

Page 229

1

[illegible]

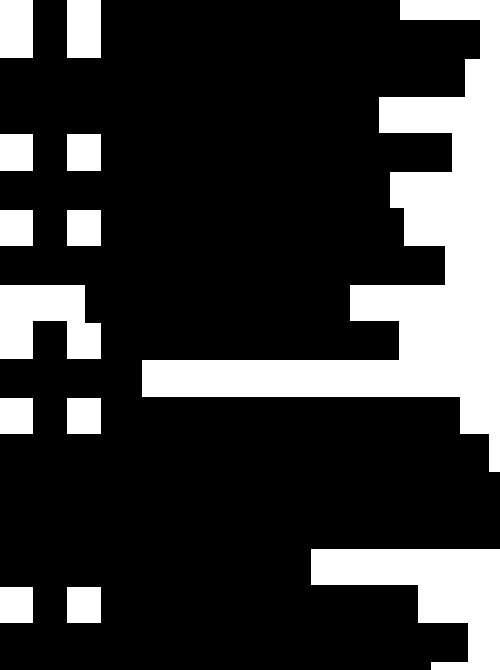
Page 232

1

[illegible]

Page 233

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Page 234

1 [REDACTED]

2 [REDACTED]

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22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 237

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 BY MR. DAVIS:

9 Q. You can answer. Was that a

10 yes?

11 A. No, no, no. I'm just

12 asking, should I answer? Okay.

13 Q. Yes.

14 MR. TRISCHLER: Dr. Gomas,

15 as I indicated at the beginning of

16 the deposition, I may place

17 objections on the record --

18 THE WITNESS: Yes, sir.

19 MR. TRISCHLER: -- and tell

20 you not to answer. Once I've

21 stated the objection, please

22 answer.

23 THE WITNESS: Thank you for

24 the clarification. Thank you.

Page 238

1 Thank you.
2 Yes, so I will answer that.
3 [REDACTED]

[REDACTED]

Page 240

1 [REDACTED]

[REDACTED]

Page 239

1 [REDACTED]

[REDACTED]

Page 241

1 [REDACTED]

[REDACTED]

20 BY MR. DAVIS:
21 Q. Is that an expectation that
22 you have?
23 MR. TRISCHLER: Excuse me.
24 Objection to the commentary.

Page 242

1 Objection to counsel's arguing --
2 argument with the witness. Also
3 object that the question has been
4 asked and answered multiple times.
5 And objection, lack of foundation,
6 given that he's told you multiple
7 times that he does not work in
8 R&D.
9 MR. DAVIS: It's not been
10 answered, frankly.
11 MR. TRISCHLER: It has,
12 John.
13 MR. DAVIS: It has not.
14 MR. TRISCHLER: Answer it
15 again, Dr. Gomas, to the extent
16 that you can.
17 BY MR. DAVIS:
18 [REDACTED]

Page 243

1 [REDACTED]

Page 244

1 [REDACTED]

13 MR. TRISCHLER: Is that a
14 closing argument or a question?
15 MR. DAVIS: It's a question.
16 I'm trying to get an answer.
17 MR. TRISCHLER: Which one?
18 Which question?
19 MR. HONIK: That's not an
20 objection. If you want to state
21 an objection, do so. Don't make a
22 speech.
23 MR. TRISCHLER: Hey, Ruben,
24 I just heard a speech. One

Page 245

1 lawyer -- one lawyer per side.
2 Stay quiet.
3 BY MR. DAVIS:
4 [REDACTED]

Page 246

[REDACTED]

Page 248

1 correct?

2 MR. TRISCHLER: Objection to

3 the form. Asked and answered.

4 THE WITNESS: May I ask you

5 to clarify whether it is for a

6 specific solvent, or are you

7 asking as a general question, sir?

8 BY MR. DAVIS:

9 Q. Sure. Let me show you

10 Plaintiff Glover-23 and 24.

11 A. Again, I was supplied some

12 documents in the break. If you could

13 kindly give me the bottom number, that

14 would be really helpful, sir.

15 (Previously marked

16 PL-Glover-23.)

17 (Previously marked

18 PL-Glover-24.)

19 BY MR. DAVIS:

20 Q. Well, that would be in the

21 exhibit binders.

22 A. Oh, okay. Sorry.

23 Q. Plaintiff Glover-23 and 24.

24 A. Yes. I have it in front of

Page 247

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 BY MR. DAVIS:

12 Q. Who would I talk to at R&D

13 to get an answer to my questions?

14 A. What is the current head of

15 R&D name, I have already given to you.

16 That is the only name that I can think of

17 as the R&D head.

18 Q. Okay. And who is that

19 again?

20 A. That is Dr. Chandra Has.

21 Chandra Has. C-H-A-N-D-R-A, H-A-S.

22 Q. Okay. The fact is that

23 Mylan did not do any process validation

24 for recovered solvents; isn't that

Page 249

1 me, sir.

2 Q. Okay. Who is MVRBS --

3 A. Subrahmanyam?

4 Q. -- Subrahmanyam? Yes.

5 A. He is a colleague from

6 quality assurance in Unit 8, sir.

7 Q. Okay. Did he report to you?

8 A. No. He reported in to the

9 quality head of the site.

10 Q. Who then reported to you?

11 A. Who then reported to the

12 cluster head.

13 Q. Who then reported to you?

14 A. Yes, sir.

15 Q. Okay. Thank you.

16 So he was within your sphere

17 of control or oversight as -- as head of

18 global quality for APIs?

19 A. I would say that he is part

20 of the quality team.

21 Q. Okay. Does he -- he reports

22 up the chain of command to you, does he

23 not?

24 A. That's true, sir.

Page 250

1 [REDACTED]

Page 252

1 [REDACTED]

Page 251

1 [REDACTED]
2 [REDACTED]

Page 253

1 [REDACTED]

Page 254

1 [REDACTED]

Page 256

1 [REDACTED]

Page 255

1 [REDACTED]

Page 257

1 [REDACTED]

Page 258

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 Q. Let's, if you don't mind,
8 flip back to Exhibit 8. Do you have that
9 handy?
10 A. Exhibit 8?
11 Q. This is the Unit 8 periodic
12 commitments.
13 A. Yes, sir. I'm just --
14 Q. Do you have it, Dr. Gomas?
15 A. I have that, yes, sir.
16 Q. Okay. Go to Page 5 of 20 of
17 that document, the numbering is in the
18 bottom center.
19 A. Yes, sir.
20 Q. Okay. Do you see under the
21 commitment column another PR column like
22 the ones that we looked at earlier,
23 PR 1908077?
24 A. Okay.

Page 259

1 Q. And just like the other
2 ones, the documents associated with that,
3 would live in Trackwise, correct?
4 A. That's right, sir.
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
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Page 260

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16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 MR. TRISCHLER: Objection.
23 Objection to the form and the
24 scope.

Page 263

1 BY MR. DAVIS:
2 Q. Did we just lose each other
3 there, Dr. Gomas? You got a little
4 choppy there for a second.
5 MR. TRISCHLER: I just said
6 objection to form and scope, John.
7 I don't know if you --
8 BY MR. DAVIS:
9 Q. Did you hear my question,
10 Dr. Gomas, or did we lose each other?
11 A. There was a little bit of
12 lagging. Sorry. If you could repeat it,
13 sir.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
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22 [REDACTED]
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Page 264

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Page 265

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13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 BY MR. DAVIS:
20 Q. So let's unpack that. What
21 you're saying is that now, as a result of
22 these learnings, regulators, including
23 the FDA now have set an expectation that
24 recovered solvent processes be validated

Page 266

1 on an individual solvent basis; is that
2 right?
3 A. That is what our
4 interpretation -- that is what our
5 learning is, yes, sir.
6 Q. Okay. And what you're
7 saying here today now is that back in
8 2018, that was not industry standard?
9 A. That is, at least to my
10 knowledge, up to that nitrosamine
11 knowledge came, I have not seen any
12 specific requirements coming neither from
13 the regulatory agencies, in my
14 experience, nor from any specific, you
15 know, comment. But once the -- once the,
16 you know, once the industry as well as
17 regulators understood about the root
18 causes that was identified for -- for,
19 you know, nitrosamine impurities, we
20 provide to do, you know, the position.
21 And we thought that this is
22 maybe an expectation that was emerging,
23 and then we took a decision to
24 incorporate this as an additional

Page 267

1 control.
2 Q. It was an expectation at the
3 time, wasn't it?
4 A. My interpretation is that
5 maybe the industry was -- so until that
6 time was following it probably. But
7 surely not an expectation from
8 regulatory, because I had not had a
9 personal experience of anyone being
10 written up for recovered solvent not
11 validated, at least to my knowledge. As
12 I said --
13 Q. So you're not aware --
14 sorry. Go ahead. I didn't mean to cut
15 you off.
16 A. I'm sorry, sir.
17 As I said, you know,
18 industry follows recovered solvent usage,
19 for the last how many years I don't
20 recollect. But, I mean, that's a
21 practice.
22 Q. Okay. You're not aware of
23 Mylan receiving any DMF deficiency
24 letters from the FDA prior to 2018

Page 268

1 saying, Your DMF is deficient because you
2 haven't put your recovered solvent
3 process in here?
4 A. I do not have -- I do not go
5 through every deficiency that may come,
6 because deficiencies are usually shared
7 between the regulatory team who receives
8 it and then provides it to the site, as
9 well as the R&D to provide response.
10 But at least a few of them
11 that would come to my notice, I do not
12 recollect anything such -- at least prior
13 to the nitrosamine solvent.
14 Q. Okay. And what about audits
15 by Mylan's API customers? Are you aware
16 of any audits prior to 2018 where a
17 customer said, "Hey, you're not -- you're
18 not doing recovery solvent process
19 validation." Are you aware of any of
20 that?
21 A. I am not have privy to all
22 of the audits of customers, but at least
23 in my -- in my general understanding and
24 knowledge, I have not come across any

Page 269

1 such reference prior to 2018 when this
2 knowledge of nitrosamines unfolded. Post
3 2018, probably yes, but not prior to
4 2018, sir.
5 Q. I'm going to publish a
6 previously marked exhibit. This isn't
7 one that would be in your --
8 MR. DAVIS: Oh, hey, Bill, I
9 think we got some more choppiness
10 here.
11 BY MR. DAVIS:
12 Q. Dr. Gomas, can you hear me?
13 A. Yes, I can hear you, sir.
14 Q. You are speeding up or
15 slowing down at least on the video a
16 little bit.
17 MR. DAVIS: So I'm going to
18 publish Plaintiff Glover-19.
19 THE WITNESS: Yes, sir.
20 (Previously marked
21 PL-Glover-19.)
22 BY MR. DAVIS:
23 Q. It's not in the documents
24 that you have, so you'll have to do it on

Page 270

1 the screen with me.
2 MR. TRISCHLER: He might
3 just -- if it helps, John, he
4 might have it, because you had
5 indicated that you might use the
6 prior exhibits so I think that --
7 MR. DAVIS: Oh, okay.
8 MR. TRISCHLER: -- I had
9 asked that they be printed out.
10 So he may have it if you want him
11 to look.
12 BY MR. DAVIS:
13 Q. Sure. Yeah. Could you see
14 if you have Plaintiff Glover-19?
15 A. Yes. I have the exhibit.
16 Yes, sir.
17 [REDACTED]

Page 271

1 [REDACTED]

Page 272

1 [REDACTED]

Page 273

1 [REDACTED]

Page 274

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

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10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 BY MR. DAVIS:

22 Q. Let me show you Plaintiff

23 Glover 22.

24 A. Yes, sir.

Page 275

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

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18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 277

1 (Previously marked

2 PL-Glover-22.)

3 BY MR. DAVIS:

4 Q. Do you see this is an e-mail

5 that you wrote on November 29, 2018?

6 A. Yes, sir.

7 Q. And the subject of it is

8 recovered solvents?

9 A. Yes, sir.

10 Q. Okay. And the attachment

11 even is recovery solvent data.pptx. Do

12 you see that?

13 A. Yes, sir.

14 Q. Do you see the second

15 sentence that you wrote, "Current

16 industry standard is to have

17 demonstration of process capability of

18 demonstration/validation"?

19 Do you see that?

20 A. Yes, sir.

21 Q. Okay. And then do you see

22 this next sentence below that, "Neither

23 of these two practices," and one of those

24 two practices is what I just read to you,

Page 278

1 "are followed in our facilities and we
2 may be challenged for this in the
3 future."
4 Do you see that?
5 A. I'm seeing that, yes, sir.
6 Q. Okay. And you wrote this --
7 this e-mail, did you not?
8 A. Right, I did write this
9 e-mail, sir.
10 Q. Okay. In 2018, November of
11 2018, correct?
12 A. That is right. Yes, sir.
13 Q. And you're referring to
14 current -- then current industry
15 standards, correct?
16 A. Yes. That is -- that is a
17 timeline when the complete understanding
18 of nitrosamines are the most, towards the
19 end of the year. So I am -- as a
20 responsible quality lead for the
21 organization, I'm giving context here,
22 saying that yes, this is what we're
23 learning and this is what the industry is
24 thinking, we need a choice of what is

Page 279

1 current, but it is -- it is to be
2 understood in a context, sir.
3 We are at the end of the
4 year, where we already have understood,
5 the industry has understood very well,
6 you know, the nitrosamine root causes and
7 the work requirements have come, what are
8 the levels that are allowed as to the new
9 guidelines, so the new controls are
10 emerging, so I'm making a pitch to my
11 team, saying that this is something which
12 you need to start doing it. Let's make a
13 CAPA of this.
14 So this -- this is an
15 internal communication. The language is
16 based on, you know, certain strategy or,
17 you know, the way I want to address. But
18 the basic theme and that essence is that
19 this is a new expectation, let us start
20 doing it.
21 Q. Okay. You're saying it's a
22 current expectation though, in your
23 e-mail, correct?
24 A. Maybe I would have used

Page 280

1 current because at that time the
2 reference or the situation or the time
3 frame is that we are post understanding
4 nitrosamine. So that is -- that is why
5 maybe the word "current" was in my mind,
6 because this is a scenario
7 post-nitrosamine.
8 Q. This is -- this is roughly
9 -- this is a matter of days after Mylan
10 recalled its valsartan, correct?
11 A. That also shows our
12 earnestness to get to the new
13 requirements quickly and show that we --
14 we correct them and we improve. So
15 that -- that should be taken as a
16 positive note, that -- that quality head
17 is reacting such to our position that
18 these are improvements that we need to
19 do. And I would always discharge my
20 duties that way.
21 Q. I appreciate that. But
22 didn't you testify earlier that both
23 Unit 7 and Unit 8 remain under OAI
24 designation to this day?

Page 281

1 MR. TRISCHLER: Objection.
2 Asked and answered.
3 THE WITNESS: As I -- as I
4 previously said, sir, OAI has got,
5 you know, several, you know, the
6 way you can, you know, interpret.
7 So from an FDA standpoint,
8 when they -- when they say that it
9 is an official action initiated,
10 they would have -- they may have
11 something in their mind what they
12 would like to achieve from that.
13 But from a -- from a safety
14 standpoint or a risk of using a
15 side standpoint, if they have
16 decided that it is risky to use,
17 continue to use our manufacturing
18 site for providing lifesaving
19 medicine to people, they wouldn't
20 allow us to manufacture
21 continuously and deliver the
22 products for the patients.
23 So OAI from an FDA
24 standpoint, I'm not qualified to,

Page 282

1 you know, comment, what the what
2 intention and purpose and the tool
3 they use.
4 But from a simple quality
5 assurance person and professional,
6 I would say that FDA, irrespective
7 of the OAI categorization, has
8 deemed, you know, that our
9 facility is safe to operate, our
10 medicines are safe for
11 consumption, and Unit 7, Unit 8,
12 irrespective of being a warning
13 letter and OAI, continues to
14 manufacture essential medicines
15 and supplies to U.S., as well as
16 across the world.
17 BY MR. DAVIS:
18 Q. What's the next step after
19 OAI? What would be the next punishment
20 the FDA could levee?
21 MR. TRISCHLER: Objection to
22 form.
23 THE WITNESS: I think --
24 yeah, I think I wouldn't say that

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1 kind of word, because I do not
2 know what FDA would do.
3 From an industry standpoint,
4 I can tell you that once there is
5 a warning letter, if there is a
6 warning letter, once all the
7 required compliance status is --
8 you know, the CAPA is closed, we
9 will send periodic updates, as you
10 have seen.
11 And we also see meetings --
12 regulatory meetings with the FDA,
13 which we saw, we had.
14 But unfortunately, because
15 of the Covid, the FDA could not
16 travel and, you know, probably
17 come to -- for inspections of our
18 site because of the pandemic
19 situation for the last, almost one
20 year, three, four months.
21 We have regularly indicated
22 to the agency, inviting them for
23 the last year itself, officially,
24 that we have completed all the

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1 actions that we have committed, so
2 please do come and inspect us so
3 that we know that you can
4 reevaluate.
5 Meanwhile, I would also like
6 to provide you that even though
7 FDA has not come for -- or
8 provided an inspection, we already
9 had European as well as Australian
10 inspections of our Unit 8 facility
11 through virtual.
12 And then we have got
13 favorable reports in case of -- we
14 received a certificate of GMP.
15 In case of European agency
16 we have already been provided
17 reports with no particular
18 observations.
19 So -- but we are reaching
20 out to FDA and seeking them to
21 please do an inspection since last
22 year.
23 BY MR. DAVIS:
24 Q. Well, at least, let's stick

Page 285

1 with this individual solvent process
2 validation.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
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1 [REDACTED]

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1 [REDACTED]

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1 [REDACTED]

Page 289

1 [REDACTED]

Page 290

1 [REDACTED]

2 [REDACTED]

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13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 MR. TRISCHLER: John, if

21 you're going to go to a new

22 exhibit, can we take a restroom

23 break because it's been about an

24 hour and a half.

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1 MR. DAVIS: Sure, that's

2 fine. Ten minutes?

3 MR. TRISCHLER: Sure.

4 THE VIDEOGRAPHER: Going off

5 the record. 8:27 p.m.

6 (Short break.)

7 THE VIDEOGRAPHER: We are

8 back on the record at 8:43 p.m.

9 BY MR. DAVIS:

10 Q. Okay. I'm going to have you

11 pull Plaintiff Glover 58, Dr. Gomas.

12 A. Yes, sir. Yes, sir.

13 (Previously marked

14 PL-Glover-58.)

15 BY MR. DAVIS:

16 Q. Okay. Do you see that

17 that's a January 13, 2016 e-mail from a

18 gentleman I think you've mentioned today,

19 Venkata Anabathula?

20 A. Yes, sir.

21 Q. Okay. And do you see that

22 the subject is recovery solvent OOS?

23 A. Yes.

24 Q. Okay. And do you see the

Page 293

1 second sentence, "Recovered solvents are

2 not included in the scope of LIR/OOS SOPs

3 to initiate failure investigation"?

4 A. I do read that, yes, sir.

5 Q. Okay. And then the darker

6 and slightly larger text at the bottom

7 is -- do you recognize that as text that

8 he's pulled from the SOP?

9 A. It is from a different SOP.

10 Q. Okay. Which SOP is this

11 from?

12 A. He is referring to plan

13 recovery solvent management SOP.

14 Q. Okay. And which SOP are you

15 referring to where you claim that Mylan

16 did, in fact, do OOS investigations for

17 recovered solvents coming from vendors?

18 A. I think, you know, that what

19 I'm reading from this e-mail is not -- it

20 is not to me, the discussion that I had

21 with you.

22 What I understand from this

23 mail is, sir, he's referring to not

24 raising OOS investigation as I think is

Page 294

1 from internal recovered solvent. Because
2 he's also here referring to internal
3 solvent SOP, plan recovery SOP, to
4 determine what the SOP says, therefore,
5 he is not making a laboratory
6 investigation for internally recovered
7 solvent.
8 So I think if you read it
9 altogether, it implies that the standard
10 discussions based on the recovery that is
11 being performed internally.
12 Q. Okay. And my question is
13 what -- what SOP are you referring to
14 that says to do OOS investigations for
15 recovered solvents coming from vendors
16 that fail to meet spec?
17 A. I think any -- anything that
18 is coming from external, what we consider
19 as material that we receive from outside,
20 that includes the recovered solvent. So
21 the OOS SOP incorporates -- covers all
22 the raw materials and solvents.
23 So anything that comes from
24 external sources will be covered in the

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1 SOP along with it, as I said, OOS also
2 performed for all the intermediates and
3 APIs that we manufacture internally.
4 So -- so it applies to all.
5 But this gentleman who is
6 referring to this, to the best of my
7 ability when I'm reading it altogether,
8 it again talks about the -- the solvents
9 that are internally recovered, though
10 they are not going through a formal
11 investigation process, they go for
12 redistillation, and upon redistillation,
13 if it complies, they use -- that's what
14 the entire mail is writing.
15 Q. Let me have you look at the
16 very next exhibit which is Plaintiff
17 Glover 59.
18 A. Sure.
19 (Previously marked
20 PL-Glover-59.)
21 BY MR. DAVIS:
22 Q. That's the -- that's the
23 attached recovery solvent management SOP
24 to this e-mail.

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1 A. 59?
2 Q. Yes.
3 A. Yes, I have it, yeah. Yeah.
4 Q. Okay. Do you see on Page 2
5 of -- of this Section 6.0, Procedure?
6 A. Yes, sir.
7 Q. And do you see 6.1 says,
8 "Solvents shall be recovered through any
9 of the following approaches/methods."
10 And then do you see the
11 second to last bullet point, "Solvents
12 recovered by contract/job work unit," do
13 you see that?
14 A. That's right, yes, sir.
15 Q. Okay. Then if you go to
16 Section 6.5 there's some more detail on
17 handling solvents recovered by
18 contract/job work unit, do you see that?
19 A. Yes, sir.
20 Q. And then 6.5.3 refers to "a
21 written quality agreement with
22 contract/job unit shall be there with all
23 the pertinent conditions."
24 Do you see that?

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1 A. Yes, sir.
2 Q. That's referring to an
3 external vendor recovered solvents, is it
4 not?
5 A. That's right, yes, sir.
6 Q. Okay. So this -- this SOP
7 here references externally sourced
8 recovered solvents, does it not?
9 A. It does quote a limit of
10 external recovered solvents here. This
11 is an SOP that talks about recovered
12 solvent management as a whole. So it may
13 be talking about external vendors and
14 internal vendor. But when I'm talking
15 about an investigation SOP, as I said,
16 sir, it cut across all the type of
17 materials. It cut across raw materials
18 that we receive from external sources.
19 The intermediates that we manufacture.
20 The API we manufacture.
21 So that is an investigation
22 SOP that covers all type of material.
23 But this SOP, because it is talking about
24 recovered solvent and management as a

Page 298

1 whole, it talks about how the recovered
2 solvents are contracted out in this --
3 this portion.
4 Q. Okay.
5 A. So -- so there's no conflict
6 in this -- in the SOP, sir.
7 Q. Well, sure, sure. So how
8 can you be sure that, for example, that
9 Mr. Anabathula in Plaintiff Glover 58 was
10 aware that another SOP should take
11 precedence and OOS investigations, in
12 fact, should be done when he's saying in
13 2016 that they don't -- they aren't done
14 and he references only this SOP?
15 A. I think -- as I said, you
16 know, when we are reading it altogether
17 in entirety, it is -- it is absolutely
18 that is my understanding. But planned
19 recovery SOP, management SOP, given what
20 we know, based on this data we can go in
21 to redistill.
22 So he's referring about in a
23 letter that is talked about in the
24 beginning, and then they are justifying,

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1 why that, even though the SOP doesn't
2 say, and what is the reason for it, for
3 going forward with the, you know, new
4 investigation process. So it -- it
5 negates the scenario of what is
6 internally recovered, sir.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
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24 [REDACTED]

Page 304

[illegible]

Page 305

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 Q. Let's go to --
7 MR. DAVIS: I'm going to
8 mark a few exhibits for you,
9 Dr. Gomas.
10 THE WITNESS: Okay, sir.
11 MR. DAVIS: I'm marking Tab
12 25 as Plaintiff Gomas 11.
13 (Document marked for
14 identification as Exhibit
15 PL-Gomas-11.)
16 BY MR. DAVIS:
17 Q. You'll see this is an e-mail
18 from Mylan's counsel to me. Do you see
19 that?
20 A. Give me one second. I will
21 get the document.
22 (Whereupon, a discussion was
23 held off the record.)
24 MR. TRISCHLER: This

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1 document would be in the stack
2 that was copied for you this
3 morning.
4 THE WITNESS: Oh, okay.
5 MR. DAVIS: It's --
6 MR. TRISCHLER: It's tab --
7 it's tab --
8 MR. DAVIS: 25.
9 MR. TRISCHLER: 25. Thanks,
10 John.
11 THE WITNESS: Tab 25.
12 MR. DAVIS: We can go off
13 the record while he looks.
14 THE WITNESS: We can -- is
15 it an e-mail, sir?
16 MR. DAVIS: It's an e-mail
17 from Mr. Frank Stoy to me.
18 THE VIDEOGRAPHER: Off the
19 record, sir?
20 MR. DAVIS: Do you have it,
21 Dr. Gomas, or no?
22 THE WITNESS: I will need
23 maybe few seconds. Okay.
24 MR. DAVIS: Let's go off the

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1 record.
2 THE VIDEOGRAPHER: Off the
3 record. 9:00 p.m.
4 (Whereupon, a discussion was
5 held off the record.)
6 THE VIDEOGRAPHER: We are
7 back on the record at 9:03 p.m.
8 BY MR. DAVIS:
9 Q. Dr. Gomas, at the beginning
10 of Day 2 of his deposition, Mr. Glover
11 told me that he consulted with you about
12 some process validation reports that are
13 in the DMF or DMF updates.
14 Do you know what I'm
15 referring to, what conversation I'm
16 referring to?
17 A. I think I recall a
18 conversation with the counsel along --
19 Q. Okay, yeah. Don't tell --
20 okay, yeah, don't tell me what was said
21 then if counsel was present.
22 But do you recall that
23 conversation happening between -- between
24 the first and second days of the Glover

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1 deposition?
2 A. It's quite a few days back,
3 but there could be something about
4 process validation here.
5 Q. Okay. And as a result of
6 what Mr. Glover testified, which he
7 consulted with you and you referred him
8 to some process validation reports, I
9 asked counsel to provide those to me.
10 And the reason that I've
11 marked Tab 25 as Exhibit 11 is, you'll
12 see counsel is referring me to a
13 particular Bates range of documents.
14 It's about -- it looks like roughly nine
15 to ten documents. "The process
16 validation reports are found in the
17 following Bates range."
18 Do you see that?
19 A. Yes, sir.
20 Q. Okay. So I pulled the --
21 we'll go over the VLN ones first. There
22 are several that relate to VLN, several
23 that relate to VST, and a couple that
24 relate to VAA.

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1 So let's go through the VLN
2 ones first -- sorry, hold on. Let's go
3 through the VST ones first, which are
4 Tabs 26 through 29.
5 A. There is a small confusion
6 here. I have -- 26 is the VLN process
7 validation.
8 27 is voluntary recall
9 documentation. 28, 29.
10 MR. DAVIS: Okay. Let's go
11 off the record again.
12 THE VIDEOGRAPHER: Off the
13 record at 9:06 p.m.
14 (Whereupon, a discussion was
15 held off the record.)
16 THE VIDEOGRAPHER: We are
17 back on the record at 9:13 p.m.
18 BY MR. DAVIS:
19 Q. Okay. So, Dr. Gomas, we
20 were referring to Exhibit 11 and Mylan's
21 counsel providing me the process
22 validation reports that are from Bates
23 range 00895528 through 00895539.
24 Do you see those numbers

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1 referenced in that e-mail?
2 A. Yes. Sorry.
3 Q. Okay. And those include
4 process validation reports related to
5 VLN, VST, and VAA.
6 What I have pulled for you
7 are the VLN and VST reports.
8 A. Okay.
9 Q. You have seven of them, of
10 the eight of them, in front of you. I'm
11 going to mark Tab 26 as Exhibit 12.
12 (Document marked for
13 identification as Exhibit
14 PL-Gomas-12.)
15 MR. DAVIS: Tab 27 as
16 Exhibit 13.
17 (Document marked for
18 identification as Exhibit
19 PL-Gomas-13.)
20 MR. DAVIS: Tab 28 as
21 Exhibit 14.
22 (Document marked for
23 identification as Exhibit
24 PL-Gomas-14.)

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1 MR. DAVIS: And Tab 29 as
2 Exhibit 15.
3 (Document marked for
4 identification as Exhibit
5 PL-Gomas-15.)
6 BY MR. DAVIS:
7 Q. Okay. Next I'm going to --
8 Exhibit 12 is the one that you do not
9 have. So I'm going to display that on my
10 screen.
11 Can you see that, Dr. Gomas?
12 A. Yes. VST Stage I initial
13 process validation.
14 Q. Yes. That is actually going
15 to be my first question is, you were
16 involved in tracking these documents
17 down, were you not?
18 A. I have requested the site to
19 provide process validation as performed
20 using the recovered solvent. That was
21 the section, sir.
22 Q. Okay. And these are the
23 documents that they provided that counsel
24 then gave to me?

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1 A. Yes, sir.
2 Q. Okay. And those were paper
3 copy documents, were they not?
4 A. Yes.
5 Q. Okay. So they had no
6 electronic file names to them, did they?
7 A. Usually these documents are
8 printed and signed, sir.
9 Q. Okay. But there was no
10 electric -- being that it was not an
11 electronic document, there was not an
12 electronic file name for it, was there?
13 A. I don't think these are
14 electronical -- electronic filings.
15 These are all manual documentation, yeah,
16 that's why.
17 Q. Yeah. Do you know who gave
18 these documents their file names?
19 A. This -- this the -- you are
20 mentioning the -- I'm sorry, you are
21 mentioning the file name or you're
22 mentioning --
23 Q. Sure. For example, this
24 file name is 7 VST Stage I initial

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1 process validation.
2 Do you see that?
3 A. I think probably the site,
4 when they sent it to the counsel, the
5 probably attached the files and for
6 recognition they will have said what this
7 file means.
8 Q. Okay. But you're --
9 A. That's what my guess is,
10 sir.
11 Q. You don't know whether it
12 was the site or whether it was Mylan's
13 outside counsel that, in fact, gave the
14 file name to the names?
15 A. I cannot -- I cannot really,
16 because I was -- I was not involved in
17 sending it. I asked them to send it. So
18 I really do not know whether it was
19 counsel made these file names or the
20 site.
21 But I guess my guess is that
22 site would know the documents so they
23 would have said this is the file and this
24 is the document description, so --

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1 Q. Okay. But I'm not asking --
2 MR. TRISCHLER: Yeah, and
3 I'll just counsel you, Dr. Gomas,
4 don't guess. If you know, give us
5 the answer. If you don't know,
6 nobody --
7 THE WITNESS: I don't know.
8 I don't know.
9 BY MR. DAVIS:
10 Q. That's exactly what I was
11 going to say also, is, you know, I'm not
12 asking for, you know, perfect knowledge
13 of every single item here. So if you
14 don't know an answer to a question it's
15 fine to say that.
16 So you don't know who gave
17 these file names their file names?
18 A. Yes, sir, I don't know.
19 Q. Okay. Okay. Do you see
20 that the title, at least on the document
21 here, is Process Validation Report For
22 Valsartan, and that it's on Matrix's
23 header.
24 A. Yes, sir.

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1 Q. And the date is, I believe,
2 January 8, 2011?
3 A. Yes, sir.
4 Q. Okay. And the reference
5 protocol number is PVP/U-8/VST-1/10/001?
6 A. Yes, sir.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
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<div>Page 339</div> <div>1 [REDACTED]</div>	<div>Page 341</div> <div>1 [REDACTED]</div>

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1 MR. DAVIS: I need -- Clem,
2 I need an answer to my question
3 here. Like, I've let the witness
4 say what he wants to say, but I'm
5 entitled to an answer to my
6 question, which is quite limited.
7 MR. TRISCHLER: I think he
8 has answered it to the best --
9 MR. DAVIS: He has not. He
10 has not answered the question.
11 MR. TRISCHLER: You can
12 argue --
13 MR. DAVIS: Respectfully, he
14 has not.
15 MR. TRISCHLER: You can
16 argue with him and argue with me.
17 I've not instructed him not to
18 answer it again.
19 So you can --
20 MR. DAVIS: I'm asking
21 simply where the words appear in
22 the document. This is not a
23 question that requires much
24 analytical thought.

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1 It's where do the words
2 appear in the documents. And --
3 MR. TRISCHLER: Okay.
4 [REDACTED]

Page 344

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 MR. DAVIS: All right. I'm
5 going to mark Tab 30 as
6 Exhibit 16.
7 (Document marked for
8 identification as Exhibit
9 PL-Gomas-16.)
10 MR. DAVIS: 31 as
11 Exhibit 17.
12 (Document marked for
13 identification as Exhibit
14 PL-Gomas-17.)
15 MR. DAVIS: 32 as
16 Exhibit 18.
17 (Document marked for
18 identification as Exhibit
19 PL-Gomas-18.)
20 MR. DAVIS: And 33 as
21 Exhibit 19.
22 (Document marked for
23 identification as Exhibit
24 PL-Gomas-19.)

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1 BY MR. DAVIS:
2 Q. Hopefully we can get through
3 these. My question is going to be
4 roughly quite similar for these
5 documents.
6 I've got Exhibit 16 up on
7 the screen. And that's file name "3 VLN
8 Stage I initial process validation."
9 Do you see that?
10 A. Yes, sir.
11 [REDACTED]

Page 348

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Page 349

1

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Page 350

1 [REDACTED]

Page 352

1 [REDACTED]

Page 351

1 [REDACTED]

Page 353

1 [REDACTED]

Page 354

1 [REDACTED]

13 MR. DAVIS: Let's take a

14 short five-minute break. I'm at a

15 section break in my outline.

16 MR. TRISCHLER: Okay.

17 THE VIDEOGRAPHER: Going off

18 the record at 10:01 p.m.

19 (Short break.)

20 THE VIDEOGRAPHER: We are

21 back on the record at 10:09 p.m.

22 BY MR. DAVIS:

23 [REDACTED]

Page 355

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

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13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 A. This is what they've sent,

18 initial and validations, later

19 validations.

20 Q. And that's the site quality

21 team, is -- is that --

22 A. Yes, sir. The site quality

23 team.

24 Q. Do you have a name for me?

Page 357

1 A. The name is Venkat, Venkat

2 Bopana.

3 Q. Okay. Venkat again. Thank

4 you.

5 A. Yes, sir.

6 Q. Let's discuss change

7 management a little bit.

8 MR. DAVIS: I'm going to

9 publish Plaintiff Glover 14.

10 THE WITNESS: I have the

11 document in front of me, sir.

12 (Previously marked

13 PL-Glover-14.)

14 BY MR. DAVIS:

15 Q. Okay. Do you recognize this

16 as the change management process SOP as

17 it applied to Mylan Laboratory Ltd.'s

18 sites effective around December 2015?

19 A. One moment, sir.

20 There's a -- this, I think,

21 is printed from the document. So -- so

22 this is -- this document is printed the

23 24 hours from 16 December, sir. One

24 second.

Page 358

1 Yes, sir, this is -- this is
2 from December of 2015, this copy is, yes,
3 sir.
4 Q. Okay. And do you see the --
5 the purpose on Page 1 is to lay down the
6 procedure to control, review, approve,
7 implementation of all GMP changes
8 connected with the manufacturing and
9 testing of APIs during their lifecycle
10 and to formally document reviews before
11 authorizing any change for implementation
12 through Trackwise? Do you see that?
13 A. Yes, I see the purpose of
14 the document, yes, sir.
15 Q. Okay. And has Mylan used
16 this Trackwise system since you've been
17 at Mylan?
18 A. Oh, I recollect being --
19 being used since at least 2015, if not
20 earlier. It could be there around 2014
21 too. I guess so, yeah. It was there for
22 quite some time. Yes, sir.
23 Q. Do you know whether it was
24 there when you arrived at Mylan in 2011?

Page 359

1 A. I -- because I wouldn't be
2 dealing with the sites of the -- that
3 panel wasn't dealing with the sites of
4 Mylan. I was dealing with the sites
5 which are external third-party quality, I
6 probably wouldn't be able to make a
7 statement for that period of time again.
8 Q. For changes that were
9 accomplished through this SOP, would
10 there be a Trackwise file for those
11 changes as stated here?
12 A. After the implementation of
13 Trackwise, I'm confident that every
14 change that is initiated would go through
15 the, you know, Trackwise system.
16 Q. Okay. How about before
17 Trackwise. Do you know whether and --
18 and/or how such changes were documented?
19 A. Before the Trackwise system
20 it would have been a paper-based system,
21 sir.
22 Q. Okay. Are those paper files
23 still maintained by Mylan, or did they
24 get put into Trackwise or digitized in

Page 360

1 any way?
2 A. I don't have an answer. But
3 it is very highly unlikely that would
4 have been digitized, because they would
5 have been so many years of document also,
6 right.
7 Q. Would those documents be
8 still somewhere in a warehouse or
9 something like that?
10 A. All our -- all our documents
11 have a retention policy for such
12 documents. So -- so we have to look at
13 it like what is our retention policy at
14 that time for such documents like change
15 control. So I really don't want to
16 speculate like in that time what the
17 procedure was.
18 Q. And you don't know what the
19 actual retention policy was for documents
20 like change controls?
21 A. The prior two Trackwise
22 system manual, I don't -- I don't
23 remember, sir.
24 Q. Okay. How about now that

Page 361

1 Trackwise is in place, do you know, is
2 there -- is there a retention policy or
3 do the documents just live in Trackwise
4 forever?
5 A. I think the -- the documents
6 stay in Trackwise and it is backed up. I
7 do not know whether those electronic
8 information is ever deleted. I would
9 have to look at the procedures. I guess
10 it is -- it is there in Trackwise, if it
11 is electronic, since it is electronic.
12 Q. Okay. Go to Page 5 of 41 in
13 the definitions. You'll see 5.11, a GMP
14 change is defined as any change that has
15 a potential GMP impact.
16 Do you see that?
17 A. I see it.
18 Q. And did you see -- do you
19 see below it, 5.11.1, that it includes
20 changes to processes, raw materials, and
21 vendor information among other things?
22 A. Yes, sir.
23 Q. Okay. Do you know if a
24 change control was created in Trackwise

Page 362

1 or otherwise created relating to the
2 substitution of recovered solvents in
3 valsartan API?
4 A. It is purely a site
5 procedure. So I would probably -- may
6 have to check with the site whether
7 any -- any change control was made or it
8 was through the -- through the batch
9 record amendment. It would be -- it
10 would be indicated. So I really do not
11 have an answer, sir.
12 Q. Well, you would agree that
13 this change management process SOP
14 applies to Unit 8 among other MLL sites
15 in India, correct?
16 A. Yes, I agree with you. Yes,
17 sir.
18 Q. Okay. And so it's not like
19 Unit 8 could come up with their own
20 change management process that
21 contradicts this, can they?
22 A. I believe since the
23 implementation of this SOP, they should
24 be following this SOP, yes.

Page 363

1 Q. Okay. Do you know whether
2 when Mylan switched vendors for recovered
3 o-xylene for valsartan, did that -- do
4 you know if a change control event was
5 created in Trackwise or if it was prior
6 to Trackwise in paper form that way?
7 A. I think the vendor
8 qualification has got several other
9 aspects that will ensure that the vendors
10 are, you know, identified by codes and
11 the city, et cetera, et cetera.
12 But I'm not able to answer
13 for the site level, whether they would
14 take one change control for all the
15 changes or each of the items they would
16 have different change controls. So I am
17 not able to answer that extremely, you
18 know, confidently at this moment, sir,
19 without checking.
20 Q. Who would you check with?
21 A. The site quality head could
22 be able to provide, based on the actual
23 contents there.
24 Q. And who is that person

Page 364

1 again?
2 A. Venkat.
3 Q. Oh, Venkat. Okay, good.
4 A. Site quality head.
5 MR. DAVIS: I'm going to
6 mark Tab 12 as Exhibit 20. This
7 would be in -- not the exhibit
8 folders that you received, but the
9 materials in the link that I sent
10 that was passed along.
11 THE WITNESS: Yes.
12 (Document marked for
13 identification as Exhibit
14 PL-Gomas-20.)
15 THE WITNESS: The bottom
16 number, sir?
17 MR. DAVIS: Yeah, the bottom
18 number end in 716.
19 MR. TRISCHLER: Hey, John --
20 hey, John, while he's looking for
21 that, do you remember I mentioned
22 to you that I have movers coming?
23 They're here.
24 Can we take five, 10 minutes

Page 365

1 so I can talk to them and do what
2 I need to do?
3 MR. DAVIS: Sure. Let's go
4 off the record.
5 THE VIDEOGRAPHER: Off the
6 record. 10:22 p.m.
7 (Short break.)
8 THE VIDEOGRAPHER: We are
9 back on the record at 10:35 p.m.
10 MR. DAVIS: Did I mark as
11 Tab 12 as Exhibit 20 already, or
12 was I waiting to do that?
13 THE WITNESS: No, I have it
14 in my hand, sir.
15 MR. DAVIS: And Michelle
16 that's been marked as 20? Okay.
17 BY MR. DAVIS:
18 Q. Okay. Looking -- before we
19 move to that real fast, Plaintiff
20 Glover-14 which is the SOP we were
21 looking at on change management process,
22 do you see that that SOP is MLL CRP SOP
23 CQA GMP 0066 is the number?
24 A. Yes.

<p style="text-align: right;">Page 366</p> <p>1 Q. Okay. Exhibit 20 -- and</p> <p>2 I'll read you the file name because it's</p> <p>3 not on the document.</p> <p>4 The file name is MLL CRP SOP</p> <p>5 CQA GMP 0066, Attachment 7.2.</p> <p>6 A. Yes, sir.</p> <p>7 Q. Did you get that?</p> <p>8 A. Yes, sir.</p> <p>9 Q. Okay. So does that tell you</p> <p>10 that this is an attachment to the change</p> <p>11 management SOP we were looking at?</p> <p>12 A. Yes, it does.</p> <p>13 Q. Okay. Have you seen this</p> <p>14 document before?</p> <p>15 A. I could have seen it within</p> <p>16 the course of some discussion or doing an</p> <p>17 inspection, possible. But I won't</p> <p>18 recollect every word in that or sentence.</p> <p>19 I'm familiar with this SOP, yes, sir.</p> <p>20 Q. Okay. And this is -- this</p> <p>21 attachment refers to some typical</p> <p>22 examples of situations that might arise</p> <p>23 under the SOP and how to handle them?</p> <p>24 A. That's right, sir, as it</p>	<p style="text-align: right;">Page 368</p> <p>1 designated as key starting material may</p> <p>2 undergo much more, you know, rigorous,</p> <p>3 you know, evaluation in the -- in the</p> <p>4 hierarchy of regulatory requirements,</p> <p>5 vis-à-vis a recovered solvent, because</p> <p>6 the recovered solvent, as I have</p> <p>7 explained to you, sir, from the</p> <p>8 regulatory filing itself, there is no</p> <p>9 commitment for process. It is only for</p> <p>10 specification and CoA.</p> <p>11 So that change from Vendor A</p> <p>12 to Vendor B would be handled through the</p> <p>13 regular, you know, the controls from GMP</p> <p>14 and not to regulatory change management,</p> <p>15 you know, action standpoint based on --</p> <p>16 Q. What --</p> <p>17 A. -- the requirements.</p> <p>18 Q. Sorry. I didn't mean to cut</p> <p>19 you off there.</p> <p>20 So what did Mylan do for</p> <p>21 changing purely recovered solvent</p> <p>22 vendors? What actions did Mylan take for</p> <p>23 those changes, if any?</p> <p>24 A. If I recollect the whole</p>
<p style="text-align: right;">Page 367</p> <p>1 states on Page Number 36 of the SOP, yes,</p> <p>2 sir.</p> <p>3 Q. Okay. Let's start at the</p> <p>4 bottom with vendor change, 09.</p> <p>5 Do you see that?</p> <p>6 A. Yes, sir.</p> <p>7 Q. On Page 3. Do you know --</p> <p>8 and it says, "Starting material vendor</p> <p>9 changes."</p> <p>10 Do you see that?</p> <p>11 A. Yes, sir.</p> <p>12 Q. Would that include recovered</p> <p>13 solvents?</p> <p>14 A. No, sir.</p> <p>15 Q. Okay. So where would vendor</p> <p>16 changes for recovered solvents be</p> <p>17 handled?</p> <p>18 A. As I said, you know, because</p> <p>19 the change management system also is</p> <p>20 linked with the regulatory requirements</p> <p>21 too, because, for example, each starting</p> <p>22 material change needs validation prior to</p> <p>23 execution of such changes.</p> <p>24 So a raw material that is</p>	<p style="text-align: right;">Page 369</p> <p>1 management of vendor of recovered</p> <p>2 solvent, there would be a vendor</p> <p>3 qualification step for those vendors that</p> <p>4 would include inspection of the facility,</p> <p>5 technical agreements, and then testing of</p> <p>6 samples when it comes, and, you know,</p> <p>7 compliance to specification.</p> <p>8 So those are the broad</p> <p>9 elements that would be considered, you</p> <p>10 know, for such change.</p> <p>11 Q. What about filing a form</p> <p>12 356h as part of the ANDA?</p> <p>13 A. My -- my understanding from</p> <p>14 my experience -- I'm not talking from a</p> <p>15 regulatory expert standpoint. I think,</p> <p>16 you know, at least from my experience is</p> <p>17 that when a -- because there is no</p> <p>18 commitment for process for such solvents</p> <p>19 as a recovered solvent, there is no need</p> <p>20 for filing this, because the filing</p> <p>21 requirements very clearly states in the</p> <p>22 U.S. DMF requirements, for reagents and</p> <p>23 solvents, only two documents are required</p> <p>24 to be filed, specification, test results</p>

Page 370

1 CoA.
2 Q. Where are you pulling that
3 from?
4 A. It is guideline for filing
5 DMF based on GDUFA -- I don't exactly
6 remember the title, sir.
7 Q. Is it one of the -- is it an
8 ICH document --
9 A. No, sir. It's not an ICH
10 document. I think it is the FDA
11 guidelines for filing DMFs. I think it
12 is a GDUFA based guidelines.
13 Q. GDUFA?
14 A. Yeah, the GDUFA. I remember
15 seeing the guidances for -- too. But it
16 is a guideline for the industry. What
17 are -- what are the documents that need
18 to be there in a DMF and what
19 requirements for different types of
20 materials.
21 Q. So you're saying that your
22 understanding is that Mylan wasn't
23 required to file its recovered solvent
24 vendors as part of the ANDA or the DMF

Page 371

1 and so it didn't?
2 A. Yeah, I'm talking from the
3 DMF standpoint, sir, from an API
4 manufacturing standpoint, that the
5 filings for DMF filing, that's not
6 mandated beyond CoA and the
7 specification.
8 Q. Okay. And that CoA and
9 specification, that's not vendor specific
10 is what you're saying?
11 A. It is not specifically
12 mentioned like whether it should be
13 vendor or ours. Because when we look at
14 the previous section in the guidelines,
15 sir, under key starting material, raw
16 material, there are two requirements, in
17 addition to all the requirements
18 mentioned, that is, you have to have
19 vendor CoA and the manufacturer CoA. I
20 mean that is the DMF CoA.
21 But when it comes to
22 solvent, it simply says specification and
23 CoA. So generally it is a specification
24 and CoA is what Mylan would test would go

Page 372

1 into the, you know, generally would go
2 into the DMF in my -- in my
3 understanding.
4 Q. Okay. So, and I'm just
5 trying to follow you here because this is
6 some technical stuff.
7 A. Yes, sir.
8 Q. You're saying that your
9 understanding is that Mylan was not
10 required to list any vendor information
11 for recovered solvents in the DMF, and so
12 it did not, in fact, list vendor
13 information for its recovered solvents in
14 the DMF for valsartan?
15 A. My -- my clarification is
16 that, you know, it is under the title
17 Solvents and Reagents. So -- so that is
18 a typo. So it doesn't distinguish
19 between fresh or recovered, but for the
20 solvents, whether it is fresh or
21 recovered, that is what we preferred.
22 But the requirement is the specification
23 and CoA is the guidelines that I know.
24 [REDACTED]

Page 373

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 A. I'm sorry, I don't
15 recollect. I can't recollect.
16 Q. No worries. I can help you
17 out there.
18 MR. DAVIS: I'm marking
19 Tab 75 as Exhibit 21.
20 (Document marked for
21 identification as Exhibit
22 PL-Gomas-21.)
23 THE WITNESS: Is it
24 something that you would like to

Page 374

1 show, sir, or I can pick out from
2 my --
3 BY MR. DAVIS:
4 Q. Oh sure. Well, here, I'll
5 just -- it's only a two, two or
6 three-page e-mail, so I'll just share my
7 screen with it, if you can't find it.
8 A. I appreciate it, sir. I
9 appreciate it.
10 Q. Okay. Do you have -- do you
11 see that?
12 A. Yes, sir.
13 Q. Okay. So I'm going to
14 scroll down to the bottom, and you'll see
15 that there's an e-mail titled Forward
16 Lantech data - 2011 to 2019. Do you see
17 that?
18 A. Yes, sir.
19 Q. And it's to Mr. Vasireddy
20 who we just discussed off the record,
21 right?
22 A. Yes, sir.
23 [REDACTED]

Page 375

1 [REDACTED]

Page 376

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Page 392

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1. **Identify the main purpose of the document.**
 2. **Summarize the key points or findings.**
 3. **Identify the author(s) and their credentials.**
 4. **Identify the date and location of the document.**
 5. **Identify the audience or intended readers.**
 6. **Identify the main arguments or conclusions.**
 7. **Identify the supporting evidence or data.**
 8. **Identify the limitations or weaknesses of the study.**
 9. **Identify the implications or recommendations.**
 10. **Identify the sources or references used.**

Page 393

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Page 397

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2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 MR. DAVIS: Can we take a

10 short break. I'm going to --

11 let's go off the record.

12 THE VIDEOGRAPHER: Off the

13 record, 11:11 p.m.

14 (Short break.)

15 THE VIDEOGRAPHER: We are

16 back on the record at 11:14 p.m.

17 MR. DAVIS: Okay. I have a

18 lot more I'd like to do,

19 Dr. Gomas, with two minutes and

20 30 seconds left.

21 I'm just going to do one

22 thing which is, I'm marking Tab 68

23 as Exhibit 24.

24 (Document marked for

<p>Page 398</p> <p>1 identification as Exhibit 2 PL-Gomas-24.) 3 BY MR. DAVIS: 4 Q. Then I'll publish this to 5 you. Do you see this? 6 A. Yes, sir. 7 Q. Okay. All I want to do is 8 what's called authenticate this document. 9 And so, I would have more 10 questions about it, but all I -- all I 11 want to do right now is just confirm. 12 Can you confirm that you 13 wrote this e-mail at the top and received 14 the e-mail below it? 15 A. It looks like I have sent 16 this e-mail, but is it okay if I read it 17 for a second? 18 Q. Sure. Absolutely. 19 A. Thank you, sir. Yes, sir. 20 Q. Can you confirm that you are 21 the author of the top e-mail and a 22 recipient of the bottom e-mail on 23 Exhibit 24? 24 A. Yes, sir. Yes, sir.</p> <p>Page 399</p> <p>1 MR. DAVIS: Okay. I feel 2 like that's all I can accomplish 3 in two minutes and however much 4 remaining. 5 So with that, that's all I 6 have today, Dr. Gomas, and thank 7 you for your time. I know it's 8 late there. I got an early start 9 here. 10 So thank you very much. 11 And I'll pass the witness. 12 THE WITNESS: Thank you so 13 much for your time. Thank you. 14 Appreciate it. 15 MR. TRISCHLER: We'll 16 reserve -- sorry, sorry, 17 Dr. Gomas. 18 We'll reserve questioning 19 and the witness will read the 20 transcript. 21 THE VIDEOGRAPHER: That 22 concludes today's deposition. 23 The time is 11:16 p.m. 24 *****</p>	<p>Page 400</p> <p>1 (Excused.) 2 (Deposition concluded at 3 approximately 11:16 p.m., India 4 Standard Time.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p> <p>Page 401</p> <p>1 2 CERTIFICATE 3 4 5 I HEREBY CERTIFY that the 6 witness was duly sworn by me and that the 7 deposition is a true record of the 8 testimony given by the witness. 9 10 It was requested before 11 completion of the deposition that the 12 witness, ANTONY RAJ GOMAS, Ph.D., have 13 the opportunity to read and sign the 14 deposition transcript. 15 16 MICHELLE L. GRAY, 17 A Registered Professional 18 Reporter, Certified Shorthand 19 Reporter, Certified Realtime 20 Reporter and Notary Public 21 Dated: April 13, 2021 22 23 (The foregoing certification 24 of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>
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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 405, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

ANTONY RAJ GOMAS, Ph.D. DATE _____

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

Page 405

LAWYER'S NOTES

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Exhibit 93

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER
12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

14 :
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 VOLUME II
 - - -
 May 28, 2021
 - - -

Continued videotaped remote
deposition of JUN DU, taken pursuant to
notice, was held via Zoom
Videoconference, beginning at 9:12 a.m.,
EST, on the above date, before Michelle
L. Gray, a Registered Professional
Reporter, Certified Shorthand Reporter,
Certified Realtime Reporter, and Notary
Public.

- - -

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877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Page 218

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 1 (Interpreter)
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 3 Evelyn Yang Garland
 4 (Check Interpreter)
 5 Phil Hughes
 6 (Check Interpreter)
 7
 8 VIDEOTAPE TECHNICIAN:
 9 (Judy Diaz)

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- - -
I N D E X
- - -

Testimony of:
 By Mr. Slater JUN DU 226

- - -
E X H I B I T S
- - -

NO.	DESCRIPTION	PAGE
ZHP-433	Isolation and Identification Of Process Impurities (Jing Nie)	244
ZHP-434	E-mail Thread 11/2/18 Subject, Happy Chinese New Year!	275
	ZHP 00675949-56	

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- - -
P R E V I O U S L Y M A R K E D
E X H I B I T S
- - -

NO.	DESCRIPTION	PAGE
ZHP-204	Deviation Report ZHP 00004352-71	287
ZHP-212	Investigation Report 6/6/18 ZHP 00662283-09	251
ZHP-213	Warning Letter 11/29/18 ZHP 01344159-64	234
ZHP-312	Establishment Inspection Report 7/23/18 PRINSTON 00162349-06	230
ZHP-319	E-mail Thread 7/17/18 Subject, Hello and Help CHARLESWANG 000447-49	280
ZHP-321	Concise International Chemical Assessment Document 38 NDMA WHO 2002	288

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- - -
D E P O S I T I O N S U P P O R T I N D E X
- - -

Direction to Witness Not to Answer
 PAGE LINE
 None.

Request for Production of Documents
 PAGE LINE
 None.

Stipulations
 PAGE LINE
 None.

Questions Marked
 PAGE LINE
 None.

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- - -

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz, I'm a legal videographer for Golkow Litigation Services.

Today's date is May 28, 2021, and the time is 9:12 a.m.

This remote video deposition is being held in the matter of valsartan, losartan, and irbesartan products liability litigation MDL.

This is the continuation of the deponent Jun Du.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray.

The witness and interpreter

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1 are already under oath.
2 - - -
3 ... YANG SHAO and EVELYN
4 YANG GARLAND, having been
5 previously duly sworn, translated
6 Chinese to English, as follows:
7 - - -
8 ... JUN DU, having been
9 previously sworn, was examined and
10 testified as follows:
11 - - -
12 CONTINUED EXAMINATION
13 - - -
14 BY MR. SLATER:
15 Q. On the screen we have
16 Exhibit 430.
17 Let's look at the bottom
18 paragraph on the first page please.
19 This is your letter to the
20 FDA August 26, 2018.
21 The bottom paragraph says --
22 MR. SLATER: I'm sorry.
23 I'll start over.
24 THE WITNESS: Can you give

Page 227

1 me a few seconds to take a look at
2 this document?
3 BY MR. SLATER:
4 Q. Yeah, all right. I didn't
5 even -- I was halfway through my question
6 so I'll start over. But you can go ahead
7 and look first.
8 MR. SLATER: Keep track of
9 the time, please.
10 THE WITNESS: I'm ready.
11 BY MR. SLATER:
12 Q. Looking now at Exhibit 430,
13 which is your August 26, 2018 letter to
14 the FDA. I want to look at the bottom
15 paragraph on Page 1.
16 You wrote in this letter,
17 "One of the key questions about this
18 inspection as well as about our own
19 investigation is," quote -- and quoting
20 what the FDA asked -- "why NDMA was not
21 detected or considered during the process
22 change from the triethylamine process to
23 zinc chloride process."
24 Do you see where that's

Page 228

1 stated at the bottom of the letter?
2 A. Yes.
3 Q. One thing I just want to
4 clarify is, in retrospect you also found
5 out that there was NDMA and NDEA from the
6 TEA process, the triethylamine process
7 with sodium nitrite quenching. It turned
8 out that also had the nitrosamine
9 contamination, correct?
10 A. One, that question was
11 responded at that time. The issue of TEA
12 or NDEA was not discovered yet. Besides
13 NDEA is not a contaminant, it is an
14 impurity rather.
[REDACTED]

Page 229

[REDACTED]

21 MR. SLATER: Cheryll, let's
22 digress for a moment and go to
23 Exhibit 312, please, and then
24 we'll come back to this document.

Page 230

1 Let's go if we could, to the
2 cover first.
3 (Previously marked Exhibit
4 ZHP-312.)
5 BY MR. SLATER:
6 Q. Looking at Exhibit 312, this
7 is the FDA establishment inspection
8 report for the inspection from July 23,
9 2018 to August 3, 2018. Do you see that
10 on the screen?
11 A. Hold on, let me take a look.
12 Excuse me, what exhibit
13 number is this?
14 Q. 312.
15 A. Thank you. I see it.
16 Q. Let's go, if we could, to
17 Page 25 of 58; the Bates number at the
18 bottom is Princeton00162373 for that page.
19 Perfect.
20 A. Please allow me a few
21 seconds to review this EI report.
22 MR. SLATER: Keep track of
23 the time, please.
24 THE WITNESS: I'm ready. I

Page 231

1 just finished reviewing.
2 BY MR. SLATER:
3 Q. Looking now at the
4 paragraph, the short paragraph --
5 rephrase.
6 Looking at the paragraph in
7 the middle of the page which is reciting
8 the discussions with the FDA
9 investigators, it states in part,
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 232

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 Q. Let's go back to Exhibit 430
9 please. Let's look now at Page 2 of the
10 letter.
11 Let's look now at the third
12 paragraph on the page, please. Can
13 you -- rephrase.
14 Your letter to the FDA
15 states in the third paragraph on Page 2,
16 in the current -- excuse me, I've got to
17 start over.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 233

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 A. What are you referring to by
18 "the company"?
19 Q. ZHP, who you were -- who you
20 were writing on behalf of -- rephrase.
21 ZHP, on whose behalf you
22 were writing this letter as executive
23 vice president.
24 A. That is correct. That's

Page 234

1 what ZHP wrote.
2 Q. You signed the letter as
3 executive vice president of the company,
4 right?
5 A. That is correct. I signed
6 this letter on behalf of ZHP.
7 MR. SLATER: Let's go now,
8 Cheryll if we could to
9 Exhibit 213, the FDA's response.
10 (Previously marked Exhibit
11 ZHP-213.
12 BY MR. SLATER:
13 Q. On the screen we have
14 Exhibit 213, which is the FDA's
15 November 29, 2018 letter written in
16 response to your August 26, 2018 letter
17 that we were just discussing.
18 A. Could you give me a few
19 seconds to review this document. I am
20 ready.
21 Q. First of all, in the middle
22 of the first page the fourth paragraph
23 down states, "We reviewed your August 26,
24 2018 response in detail and acknowledge

Page 235

1 receipt of your subsequent
2 correspondence."
3 The August 26th letter is
4 the letter we were just discussing prior
5 to this document, correct?
6 A. That is correct.
7 Q. Just above the sentence that
8 I just read, the FDA informed you, on
9 November 29, 2018, "Because your methods,
10 facilities, or controls for
11 manufacturing, processing, packing, or
12 holding do not conform to cGMP, your API
13 are adulterated within the meaning of
14 Section 501(a)(2)(B) of the Federal Food,
15 Drug, and Cosmetic Act, 21 U.S.C.
16 351(a)(2)(B)."
17 Do you know what adulterated
18 means?
19 A. I do.
20 Q. What does adulterated mean?
21 A. What they meant was that it
22 was involved in a fraud or fake
23 substance. However, this is their
24 uniform statement in the warning letter.

Page 236

1 If you try to find out what they
2 specifically referred to, you have to
3 resort to the text below.
4 MR. GOLDBERG: Just note my
5 objection to the last question as
6 calling for a legal conclusion.
7 BY MR. SLATER:
8 Q. Going up one more paragraph,
9 there's a single sentence paragraph that
10 says, "This warning letter summarizes
11 significant deviations from current good
12 manufacturing practice (cGMP) for active
13 pharmaceutical ingredients (API)."
14 And what I'd like to now do
15 is go through one of the specifics. If
16 we can turn now to Page 4 of the letter,
17 which the Bates stamp is ZHP01344162 for
18 that page so we can look at one of the
19 specific examples.
[REDACTED]

Page 237

[REDACTED]

<div>Page 238</div> <div>[REDACTED]</div>	<div>Page 240</div> <div>[REDACTED]</div>
<div>Page 239</div> <div>[REDACTED]</div>	<div>Page 241</div> <div>[REDACTED]</div>

Page 242

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 243

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 most important rule that you need to
8 follow, and that ZHP needed to follow, in
9 manufacturing drugs for sale to patients?
10 MR. GOLDBERG: Objection to
11 form. Misstates testimony.
12 THE WITNESS: To any drug
13 manufacturer, ensuring the
14 product -- let me put it this way.
15 Let me start all over again.
16 To any drug manufacturer
17 utilizing their utmost knowledge
18 and effort to ensure the safety to
19 the patient for any of their
20 product is correct.
21 This statement is correct.
22 MR. SLATER: Cheryll, I want
23 to go to another document. Don't
24 lose this. We'll come right back

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1 to it.
2 I want to go to an article
3 titled Isolation and
4 Identification of Process
5 Impurities in Crude Valsartan.
6 There we go.
7 Just for the record what
8 exhibit number is this?
9 MS. CALDERON: 433.
10 (Document marked for
11 identification as Exhibit
12 ZHP-433.)
13 BY MR. SLATER:
14 Q. 433. Thank you.
15 Looking now at Exhibit 433,
16 this is an article that was published in
17 the Journal of Liquid Chromatography &
18 Related Technologies in 2006.
19 And if we could, let's go to
20 the second page so we can see who the
21 authors are.
22 Do you see there's three
23 authors, and the third one is Danhua Wang
24 from ZHP?

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1 A. I see it.
2 Q. So this is an article
3 published in 2006 in a medical journal
4 and one of the authors was a ZHP
5 employee. You see that, correct?
6 A. I see it. However, could
7 you please give me a few seconds to
8 review this document, because I've never
9 seen this document before, nor do I have
10 the relevant technical knowledge.
11 MR. SLATER: Let's keep time
12 on this.
13 THE WITNESS: I'm ready.
14 BY MR. SLATER:
15 Q. Looking at the introduction
16 to this 2006 article authored in part by
17 a ZHP employee, it starts out stating,
18 "The quality and safety of
19 pharmaceuticals can be significantly
20 effected by the presence of impurities."
21 Do you see what I just read?
22 A. That's correct. That's what
23 it says here.
24 Q. In the case of ZHP's

Page 248

■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]

(b) (5) DPP

I: [REDACTED]
B: [REDACTED]

I _____

■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]

☐ [redacted]
☐ [redacted]

Age Group	Percentage
18-24	10
25-34	20
35-44	30
45-54	40
55-64	50
65-74	60
75-84	70
85+	80

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§ 87(2)(b) [REDACTED]

■ [REDACTED]
■ [REDACTED]
■ [REDACTED]

☐ I am a member of the following organization(s):
☐ _____
☐ _____
☐ _____
☐ _____

- [REDACTED]
- [REDACTED]

☐ [redacted] [redacted]

■ [REDACTED]

■ [REDACTED]

[illegible]

Page 250

[REDACTED]

Page 252

1 MR. SLATER: Sure.
2 MR. GOLDBERG: Thank you.
3 MR. SLATER: Let's go off
4 the record.
5 THE VIDEOGRAPHER: The time
6 right now is 10:08 a.m.
7 We're off the record.
8 (Short break.)
9 THE VIDEOGRAPHER: The time
10 right now is 10:12 a.m. We're
11 back on the record.
12 BY MR. SLATER:
[REDACTED]

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[REDACTED]

16 MR. SLATER: Okay. We can
17 take that document down now.
18 Let's go to Exhibit 212.
19 (Previously marked Exhibit
20 ZHP-212.)
21 MR. GOLDBERG: Adam, if
22 you're in between documents, can
23 we just take a two-minute break,
24 not a long break?

Page 253

[REDACTED]

Page 254

[REDACTED]

Page 256

[REDACTED]

Page 255

[REDACTED]

Page 257

[REDACTED]

Page 258

[REDACTED]

Page 260

[REDACTED]

Page 259

[REDACTED]

Page 261

[REDACTED]

Page 262

[REDACTED]

Page 264

[REDACTED]

Page 263

[REDACTED]

Page 265

[REDACTED]

Page 266

[REDACTED]

Page 268

[REDACTED]

24 MR. SLATER: Let's go --

Page 267

[REDACTED]

Page 269

1 Cheryll, let's take -- oh. We're
2 actually in this document. Can
3 you go back to the fourth page of
4 this document, please,
5 Exhibit 213?
6 Perfect.
7 BY MR. SLATER:
[REDACTED]

Page 270

11 MR. SLATER: Cheryll, let's
12 go to Exhibit 212, please.
13 BY MR. SLATER:
14 Q. Exhibit 212 is a draft of
15 the deviation investigation report titled
16 Investigation Regarding an Unknown
17 Impurity (Genotoxic Impurity).
18 Do you see that on the
19 screen?
20 A. That is correct.
21 I would request a few
22 seconds to review this document.
23 MR. SLATER: Keep time on
24 this, please.

Page 271

1 THE WITNESS: I am ready. I
2 have finished the review.
3 BY MR. SLATER:
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 272

16 MR. SLATER: Cheryll, let's
17 go back to Exhibit 430. Page 2.
18 Third paragraph. The fifth line
19 down.
20 BY MR. SLATER:
21 Q. You said, "It is this extra
22 dimension over the current industry
23 practice that obscured us from foreseeing
24 this impurity during the process change

Page 273

1 from triethylamine process to zinc
2 chloride process."
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 274

[REDACTED]

Page 276

[REDACTED]

Page 275

[REDACTED]

4 MR. SLATER: Let's go off
5 the record.
6 THE VIDEOGRAPHER: The time
7 right now is 11:02 a.m. We are
8 off the record.
9 (Short break.)
10 THE VIDEOGRAPHER: The time
11 right now is 11:17 a.m. We're
12 back on the record.
13 MR. SLATER: Cheryl, let's
14 go to the document ZHP00675949.
15 What exhibit number is this
16 now?
17 (Document marked for
18 identification as Exhibit
19 ZHP-434.)
20 MS. CALDERON: 434.
21 MR. SLATER: Thank you.
22 BY MR. SLATER:
[REDACTED]

Page 277

[REDACTED]

Page 278

[REDACTED]

Page 280

[REDACTED]

10 A. Based on the current
11 exchange rate, 1 USD is equivalent to
12 6.4 rmb based on which you can do a
13 simple calculation.
14 MR. SLATER: Let's go to
15 Exhibit 319, please.
16 (Previously marked Exhibit
17 ZHP-319.)
18 THE WITNESS: Can you allow
19 me to find this document in the
20 link.
21 I have found it. Can you
22 give me a few seconds to review
23 it?
24 MR. SLATER: Fine. We keep

Page 279

[REDACTED]

Page 281

1 track of all the time. We can
2 take whatever time you need.
3 THE WITNESS: I'm ready.
4 BY MR. SLATER:
[REDACTED]

Page 282

[REDACTED]

Page 284

[REDACTED]

4 BY MR. SLATER:

5 Q. Have you seen the deposition

6 testimony given from Min Li?

7 A. Would you please repeat your

8 question?

9 Q. Have you seen Min Li's

10 deposition transcript and read what he

11 testified to about your interactions with

12 Charles Wang?

13 A. No, I've not seen it.

14 Q. Were you on calls with

15 Charles Wang and Min Li together where

16 all three of you spoke?

17 A. Are you suggesting that we

18 discussed as a group, the three of us?

19 Q. Did you, Charles Wang, and

20 Min Li discuss the NDMA contamination of

21 valsartan together on conference calls or

22 in WeChat?

23 A. First of all, I do not agree

24 with your statement that NDMA is a

Page 283

[REDACTED]

Page 285

1 contaminant.

2 Secondly, I believe there

3 was some discussion among the three of us

4 in WeChat.

5 MR. SLATER: Take that

6 document down. Let's go to

7 Exhibit 210.

8 It's not coming up on my

9 screen for some reason. There we

10 go.

11 BY MR. SLATER:

12 Q. Looking now at Exhibit 210.

13 This is the deviation investigation

14 report prepared November 5, 2018,

15 according to the front of the document.

16 This was an official report

17 prepared by ZHP with regard to the

18 nitrosamine contamination of the

19 valsartan, correct?

20 A. It is about an investigation

21 regarding unknown impurity of valsartan

22 API TEA process.

23 MR. SLATER: Let's go to

24 Page 11 of 236, please.

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1 Actually, let's go to
2 Page 10 first, Cheryll.
3 THE WITNESS: Please allow
4 me some time to scroll to this
5 page.
6 MR. SLATER: Keep time on
7 this as well please.
8 THE WITNESS: I am ready.
9 BY MR. SLATER:
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 287

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 MR. SLATER: Cheryll, is it
5 possible, this might take you a
6 moment, can you try to also pull
7 up Exhibit 204, please.
8 (Previously marked Exhibit
9 ZHP-204.)
10 THE WITNESS: Hold on. Let
11 me open this document too, from
12 the link.
13 MR. SLATER: That's not the
14 version that I have in front of
15 me, marked as 204.
16 This is a problem. All
17 right.
18 THE WITNESS: I don't see
19 that.
20 MR. SLATER: No, take --
21 take the document down.
22 All right. Let's go now to
23 Exhibit 321, which is the World
24 Health Organization article that

Page 288

1 was referenced in the deviation
2 investigation report.
3 This is Exhibit 321.
4 (Previously marked Exhibit
5 ZHP-321.)
6 THE WITNESS: Hold on. I
7 don't see that in the link.
8 Okay. I see it.
9 Could you allow me a few
10 seconds to review this document?
11 I am ready, but I cannot
12 understand this document.
13 BY MR. SLATER:
14 Q. Let's go to Page 23, please.
15 Top of the page.
16 A. Hold on. Let me scroll to
17 Page 21.
18 MR. GOLDBERG: I think it's
19 23, Jun.
20 THE WITNESS: I'm ready.
21 I'm on this page.
22 BY MR. SLATER:
23 Q. Looking at the top of
24 Page 23 in this article that was cited in

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1 ZHP's own deviation investigation report,
2 it states in the top right, "Therefore,
3 owing to the considerable evidence of
4 carcinogenicity of NDMA in laboratory
5 species, evidence of direct interaction
6 with DNA consistent with tumor formation,
7 and the apparent lack of qualitative
8 species-specific differences in the
9 metabolism of this substance, NDMA is
10 highly likely to be carcinogenic to
11 humans."
12 And that language again is
13 found in an article cited by ZHP in its
14 own deviation investigation report,
15 correct?
16 A. It does not sound the same
17 as the quote you just provided. I did
18 not make the comparison myself.
19 Q. Are you saying that I didn't
20 read the language accurately?
21 A. What you just quoted from
22 this document was right.
23 Q. The World Health
24 Organization article from 2002 concluded

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1 that NDMA is highly likely to be
2 carcinogenic to humans, correct?
3 A. Judging from what it says in
4 this document, the statement you just
5 made is correct.
6 MR. SLATER: Cheryll, can
7 you go back to Exhibit 204,
8 please. I'd like to get to the
9 part where the deviation report,
10 DCE-18001 begins.
11 THE WITNESS: Hold on. Give
12 me some time to review.
13 MR. SLATER: You can do
14 whatever you want. I'm just
15 getting to the document where I
16 want to use it.
17 THE WITNESS: So what's the
18 exhibit number again --
19 MR. SLATER: 204.
20 THE WITNESS: What I opened
21 from the link is different from
22 what you're showing on the screen.
23 BY MR. SLATER:
24 Q. You need to scroll 12 pages

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1 in and you'll find this page.
2 MR. SLATER: Please keep
3 track of all this time. I'm
4 literally going to bring him to
5 one page and identify that the WHO
6 article is identified again. So
7 all this time is unnecessary.
8 MR. GOLDBERG: Counsel, you
9 keep doing that and it is --
10 you're the one directing the
11 witness to the documents.
12 The -- he is scrolling
13 through, and he has told you that
14 he can't find the page you're
15 referring to. Okay.
16 You've got to give the
17 witness a chance to look at the
18 document and get to the page.
19 MR. SLATER: Nobody is
20 stopping him from doing that. The
21 page that I'm --
22 MR. GOLDBERG: This is your
23 time and we're -- and your
24 continual reference to the time,

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1 you don't have to do it every
2 single time the document goes up.
3 Your people are taking -- keeping
4 that time.
5 THE WITNESS: Can you repeat
6 the exhibit number? I go to
7 Exhibit 204, but the one that I
8 see is different from what you
9 have shown.
10 BY MR. SLATER:
11 Q. This is the exhibit. It's
12 Page 12 of the exhibit.
13 A. I would like you to tell me
14 the exhibit number again? What's the
15 number, 200 and what?
16 MR. SLATER: I can't do
17 this. Cheryll, can you help him,
18 please?
19 MS. CALDERON: Mr. Du, it's
20 page -- Exhibit 204, ZHP
21 Exhibit 204.
22 And then you can just -- you
23 can actually just go to the little
24 box at the top that says "of 120."

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1 You can put in the number 12.
2 This is the front of the
3 page. Then you just scroll down
4 to the 12th page.
5 Do you see that? Right
6 there.
7 THE WITNESS: I see it. I
8 see it. We are on different
9 pages.
10 MS. CALDERON: Yes.
11 THE WITNESS: Now I see it.
12 BY MR. SLATER:
13 Q. Looking within Exhibit 204,
14 is the deviation investigation report
15 dated July 20, 2018, it's entitled
16 Investigation regarding a Suspected
17 Genotoxic Impurity of Valsartan,
18 DCE-18001.
19 Do you see that?
20 A. Yes.
21 MR. SLATER: Cheryll, please
22 turn to Page 24 of 33 within
23 this -- this document. It's
24 ZHP0004388.

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1 BY MR. SLATER:
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. And again, that World Health
23 Organization article that is cited in
24 your company's official report concluded

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1 that NDMA is highly -- highly likely to
2 be carcinogenic to humans. We just went
3 over that, correct?
4 A. That is correct.
5 MR. SLATER: Thank you. I
6 have no further questions at this
7 time, subject to my right to
8 request continuation or additional
9 testimony based on motion practice
10 subsequent to the deposition.
11 Thank you.
12 MR. GOLDBERG: We'll take a
13 few minute break and then we'll
14 come back in. Can we go off the
15 record for a few minutes?
16 THE VIDEOGRAPHER: The time
17 right now is 11:52 a.m. We are
18 off the record.
19 (Short break.)
20 THE VIDEOGRAPHER: The time
21 right now is 12:05 p.m. We're
22 back on the record.
23 MR. GOLDBERG: We have no
24 questions for the witness at this

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1 time. Thank you.
2 MR. SLATER: Okay. Thanks
3 everybody.
4 THE VIDEOGRAPHER: The time
5 right now is 12:06 p.m. We are
6 off the record.
7 (Excused.)
8 (Deposition concluded at
9 approximately 12:06 p.m.)
10
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1
2 CERTIFICATE
3
4
5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.
9
10 It was requested before
11 completion of the deposition that the
12 witness, JUN DU, have the opportunity to
13 read and sign the deposition transcript.
14
15
16
17 MICHELLE L. GRAY,
18 A Registered Professional
19 Reporter, Certified Shorthand
20 Reporter, Certified Realtime
21 Reporter and Notary Public
22 Dated: June 2, 2021
23
24 (The foregoing certification
of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 217 - 301, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

 JUN DU DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

 Notary Public

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- - - - -
E R R A T A
 - - - - -

PAGE LINE CHANGE

REASON: _____

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LAWYER'S NOTES

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Exhibit 94

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 *****
5 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
6 AND IRBESARTAN PRODUCTS

7 LIABILITY LITIGATION Civil No.
8 19-2875

9 ***** (RBK/JS)

10 THIS DOCUMENT APPLIES TO ALL
11 CASES HON ROBERT B.
12 KUGLER

13 *****

14 - CONFIDENTIAL INFORMATION -
15 SUBJECT TO PROTECTIVE ORDER

16

17

18 Remote Videotaped via Zoom
19 Deposition of LIHONG (LINDA) LIN, commencing
20 at 7:05 a.m. China Standard Time, on the 5th
21 of May, 2021, before Maureen O'Connor
22 Pollard, Registered Diplomate Reporter,
23 Realtime Systems Administrator, Certified
24 Shorthand Reporter.

25

26 - - -

27

28 GOLKOW LITIGATION SERVICES
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30 deps@golkow.com

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32

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4	Direction to Witness Not to Answer
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16	PAGE LINE
17	None.
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1 P R O C E E D I N G S

2

3 THE VIDEOGRAPHER: We're now on

4 the record.

5 My name is Judy Diaz. I am a

6 legal videographer for Golkow

7 Litigation Services.

8 Today's date is May 5, 2021,

9 and the time is 7:05 a.m.

10 This remote video deposition is

11 being held in the matter of Valsartan,

12 Losartan, and Irbesartan Products

13 Liability Litigation MDL.

14 The deponent is Lihong Lin.

15 This is a continuation.

16 All parties to this deposition

17 are appearing remotely and have agreed

18 to the witness being sworn in

19 remotely.

20 All counsel will be noted on

21 the stenographic record.

22 The court reporter is Maureen

23 Pollard and will now swear in the

24 interpreter.

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1 EVELYN YANG GARLAND, Interpreter,

2 having been duly sworn to translate the

3 proceedings to the best of her ability,

4 translated as follows:

5

6 LIHONG (LINDA) LIN,

7 having been previously remotely sworn to tell

8 the truth, was examined and testified as

9 follows through the interpreter:

10 MR. SLATER: Chris, could you

11 put up Exhibit 202, please?

12 FURTHER EXAMINATION

13 BY MR. SLATER:

14 Q. On the screen is Exhibit 202.

15 Do you see that?

16 A. On the screen I see it, but the

17 font is really small, and it does not look

18 like there's any update.

19 Q. On the screen is Exhibit 202.

20 Do you see that? Yes or no.

21 A. Yes, I see it.

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 133

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 MS. PRISELAC: Objection. The
4 document speaks for itself.
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MS. PRISELAC: Objection.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 MR. SLATER: All right. Chris,
20 we can take that down. I'm going to
21 now skip to Exhibit 195, please. Make
22 it bigger. Perfect.
23 BY MR. SLATER:
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 MS. PRISELAC: Objection.
4 I'd ask the interpreter to wait
5 until I have a moment to make an
6 objection.
7 So my first objection -- okay.
8 Now, Adam, if you can give a moment
9 until the exhibit is going to be
10 loaded, since you're not apparently
11 loading them before directing Chris to
12 do so, so that I and the witness have
13 a time -- have time to look at them.
14 It's up here now, but you go
15 into this without giving an
16 opportunity for the document to be
17 uploaded, and this one is quite long.
18 MR. SLATER: Are you saying I
19 can't proceed, or are you telling me I
20 can proceed?
21 MS. PRISELAC: I was just
22 asking you to give a moment before
23 it's actually uploaded. Now it's
24 finally uploaded to mine.

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1 BY MR. SLATER:
2 Q. You can answer the question,
3 please.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MR. SLATER: Chris, can you
10 scroll down to the bottom part of the
11 page, please? Perfect. Thank you.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MS. PRISELAC: Objection. The
17 document speaks for itself.
18 So I'd just ask Ms. Garland
19 again to give me a moment to object
20 before you begin to translate.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MR. SLATER: Chris, please go

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1 to the second page.
2 BY MR. SLATER:
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 MS. PRISELAC: Objection.
9 Misstates the evidence, misinterprets
10 the document. The document speaks
11 itself.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 MR. SLATER: Chris, please go
16 the page where the Bates number is
17 099.
18 Jessica, I don't think that the
19 interpreter needs to instruct my
20 instructions to Chris. Do you care?
21 MS. PRISELAC: No, that's fine.
22 Ms. Garland, you don't have to
23 do that.
24 THE INTERPRETER: Okay.

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1 MR. SLATER: Chris, do you have
2 that? I want you to go to the
3 page 099, please. It's the same
4 document.
5 MR. GEDDIS: Sorry. My Zoom
6 just turned off. I'm sharing my thing
7 now.
8 MR. SLATER: Okay. Perfect.
9 Thank you. Could you make it a little
10 bit bigger?
11 BY MR. SLATER:
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 MS. PRISELAC: Objection. The
18 document speaks for itself. Objection
19 to completeness.
20 Could you just let me know what
21 page that's on?
22 MR. SLATER: I said it. 099 is
23 the Bates number.
24 MS. PRISELAC: Thank you.

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1 A. Let me take a look at this
2 document, as I'm still looking for this page.
3 MS. PRISELAC: It's page 34 of
4 the PDF.
5 (Pause.)
6 MR. SLATER: Let's go off the
7 clock if she's going to look for a
8 while. You can stay on the record,
9 we're just going to stop the clock on
10 the time, please.
11 A. I see this page. I need to
12 check the context.
13 (Witness reviewing document.)
14 A. This page, I've read the
15 context. I forgot the attorney's question
16 just now.
17 MR. SLATER: We can go back on
18 the clock.
19 BY MR. SLATER:
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 MS. PRISELAC: Objection.
2 Completeness. The document speaks for
3 itself.
4 You can go ahead and answer.
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MS. PRISELAC: Objection.
13 Argumentative.
14 She can answer.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 BY MR. SLATER:
6 Q. However, my question was not
7 what you addressed. My question is this.
8 I'll try to ask it a little differently,
9 maybe, to ask a better question.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 MS. PRISELAC: Objection.
15 Ambiguous.
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 142

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 MS. PRISELAC: Objection.
7 Compound, ambiguous.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 MR. SLATER: Let's take that
21 document down, Chris, and go to
22 Exhibit 205.
23 BY MR. SLATER:
24 [REDACTED]

Page 143

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 Do you see that?
5 MS. PRISELAC: Objection. The
6 document speaks for itself.
7 Also, I think we need a minute
8 for it to upload.
9 BY MR. SLATER:
10 Q. Tell me when I can proceed,
11 please.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MS. PRISELAC: Objection. The
19 document speaks for itself.
20 MR. SLATER: I'm going to
21 withdraw the question.
22 In the interest of time, Chris,
23 go, if you could, to 148 of 172. The
24 last four Bates numbers are 7899.

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1 Wow, that was quick. Good job.
2 Can you scroll down a little bit,
3 though? No, the other way, the other
4 down. Perfect, thank you.
5 BY MR. SLATER:
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MS. PRISELAC: Objection. The
19 document speaks for itself.
20 You can answer.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 145

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MS. PRISELAC: Objection. The
10 document speaks for itself.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 MR. SLATER: Let's go off the
6 clock.
7 MS. PRISELAC: Go back on the
8 clock.
9 MR. SLATER: I just didn't want
10 to interrupt while the translator was
11 speaking.
12 MS. PRISELAC: I understand.
13 Thanks.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 147

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MS. PRISELAC: Objection.
10 Ambiguous, the document speaks for
11 itself.
12 She can answer.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 149

1 [REDACTED]
2 MS. PRISELAC: Adam, this has
3 happened in every other deposition
4 where somebody knows some English,
5 where the witness was able to identify
6 maybe a specific technical term that
7 they're familiar with that may have
8 been mistranslated.
9 MR. SLATER: Let's go to the
10 next page, Chris, 365, please.
11 MS. PRISELAC: If you want to
12 ask Ms. Lin about her abilities under
13 oath, then you can do that rather than
14 cast aspersions.
15 MR. SLATER: I'm sorry. I
16 literally just want to go to the next
17 page.
18 BY MR. SLATER:
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

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MS. PRISELAC: Objection to
form. The document speaks for itself.

Row	Percentage
1	~10%
2	~95%
3	100%
4	~98%
5	~80%
6	~70%
7	~50%
8	~95%
9	~95%
10	~30%
11	~45%
12	~80%
13	~85%
14	~90%
15	~75%

MS. PRISELAC: Objection. The document speaks for itself.

19 MR. SLATER: I'm sorry, Evelyn.
20 Just one second. I just want to reask
21 the question. There was an objection,
22 so I'm going to ask it differently.

23 BY MR. SLATER:

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■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]
 ■ [REDACTED]

7 MS. PRISELAC: Objection. The
8 document speaks for itself.

9 BY MR. SLATER:

That is my question.

13 MS. PRISELAC: Objection. The
14 document speaks for itself.

15 She can answer.

[illegible]

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1 BY MR. SLATER:
2 Q. The chemical reactions that
3 caused the NDMA to form in the zinc chloride
4 process were scientifically known to the
5 general scientific community by 2011,
6 correct?
7 MS. PRISELAC: Objection.
8 Ambiguous.
9 She can go ahead and answer.
10 A. Well, first, I'm not expert on
11 chemistry.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MS. PRISELAC: Objection.

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1 Misstates the prior testimony.
2 She can go ahead and answer.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 MR. SLATER: Chris, put up
15 Exhibit 211, please. Thank you.
16 BY MR. SLATER:
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 Therefore, I'm showing you this
21 article from 2010, titled "Theoretical
22 Investigation of N-Nitrosodimethylamine
23 Formation from Nitrosation of
24 Trimethylamine."

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1 Do you see this article, which
2 was published in 2013 in the scientific
3 literature?
4 MS. PRISELAC: Objection to
5 form. Misstates prior testimony. The
6 document speaks for itself.
7 A. As I mentioned earlier, I'm not
8 a chemistry expert. I work on regulatory
9 affairs. Technical evaluation is the job
10 responsibility of our technical department.
11 With respect to this document, I did not see
12 it then.
13 MR. SLATER: Chris, please
14 scroll down to the "Introduction"
15 section, the bottom half of the page.
16 Perfect, perfect.
17 BY MR. SLATER:
18 Q. Looking now at Section 1, the
19 "Introduction," the second paragraph says,
20 "Because dialkyl nitrosamines are of great
21 interest in carcinogenesis, much attention
22 has been focused on their formation
23 mechanism, especially from secondary amines.
24 Consequently, NDMA is generally believed to

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1 be formed from the reactions of
2 dimethylamine," which is DMA, "and
3 nitrosating agents, such as N2O3, N2O4 and
4 ONCl."
5 Do you see what I just read
6 from this 2010 scientific article?
7 MS. PRISELAC: Objection to
8 form. The document speaks for itself.
9 She can answer.
10 A. Well, first, I did not see this
11 before.
12 Second, here it says that DMA
13 may react with nitrosating agents to form
14 NDMA. It is only talking about DMA here.
15 BY MR. SLATER:
16 Q. The paragraph continues, "In
17 addition to secondary amines, however, a wide
18 variety of tertiary amines have also been
19 demonstrated to react with nitrous acid to
20 produce N-nitrosamines in aqueous solution."
21 Do you see what I just read?
22 That's my only question. Do you see what I
23 just read?
24 MS. PRISELAC: Objection to

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1 form. The document speaks for itself.
2 Adam, are you contending that
3 this is still within her topics, or
4 can we both agree at this point that
5 you're well beyond that?
6 MR. SLATER: We disagree.
7 MS. PRISELAC: Okay.
8 A. It feels like you're testing me
9 on my chemistry. Just now I did see what is
10 written here. Well, I feel all this is about
11 chemistry mechanisms. This time here, I'm
12 not sure why you want me to read such
13 documents about chemical mechanisms. No
14 matter what, I will try my best.
15 BY MR. SLATER:
16 Q. Therefore, as of 2010, we see
17 at least one scientific article describing
18 exactly what happened to form the NDMA with
19 the zinc chloride process; DMA reacted with
20 nitrous acid and formed NDMA.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MS. PRISELAC: Objection to

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1 form. Foundation. The document
2 speaks for itself, misstates the prior
3 testimony, outside the scope of the
4 30(b)(6) topics.
5 You can answer if you are able.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 MR. SLATER: Chris, let's take
4 that down and go to Exhibit 197,
5 please.
6 BY MR. SLATER:
7 Q. In front of you is Exhibit 197,
8 which is an article from the scientific
9 literature in 2009 titled
10 "N,N-Dimethylformamide: much more than a
11 solvent."
12 Do you see the document in
13 front of you?
14 A. I see this document.
15 MR. SLATER: Chris, let's go to
16 the third page of the document,
17 Section 3 on the right-hand side. It
18 says "Source of carbon monoxide."
19 Perfect.
20 Q. Looking now -- rephrase.
21 Looking at the third page,
22 which is page 8315 in the top right,
23 Section 3 says, "DMF decomposes slightly at
24 its boiling point to afford dimethylamine and

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1 carbon monoxide, this reaction occurring even
2 at room temperature in the presence of some
3 acidic or basic materials."
4 So this article from 2009
5 pointed out that DMF can decompose and give
6 off dimethylamine, correct?
7 MS. PRISELAC: Objection.
8 Foundation, document speaks for
9 itself.
10 A. Well, again, like I said
11 before, I am not an expert on chemistry.
12 DMF is a stable solvent that is
13 used widely in industry and in chemical
14 engineering. Here it says that under acidic
15 or basic conditions, under room temperature
16 it is not stable.
17 This is what we did not know.
18 What we knew was that it is a good and stable
19 solvent, and I did not read this document
20 before.
21 BY MR. SLATER:
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 MS. PRISELAC: Objection to
12 form. Ambiguous, lack of foundation.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MS. PRISELAC: Objection to

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1 form. Lack of foundation,
2 argumentative.
3 You can answer.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MS. PRISELAC: Objection to
17 form. Ambiguous.
18 You can answer.
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 MS. PRISELAC: Objection.
6 Misstates the prior testimony, lack of
7 foundation, ambiguous.
8 You can answer.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 MR. SLATER: Let's take this
24 down and go to Exhibit 209.

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1 BY MR. SLATER:
2 Q. On the screen is Exhibit --
3 rephrase.
4 Here we have Exhibit 209, "IARC
5 Monograph" --
6 MR. SLATER: Chris, you have to
7 scroll up as I do this. Let me start
8 over.
9 Q. On the screen is Exhibit 209,
10 the IARC Monographs on the Evaluation of the
11 Carcinogenic Risk of Chemicals to Humans,
12 Some N-Nitroso Compounds, Volume 17.
13 If you'll scroll to the bottom,
14 please, you'll see that this is dated in
15 May 1978.
16 Do you see that document in
17 front of you?
18 A. Yes, I see the document that
19 you shared, but with the link I have -- is it
20 a very large document? It's taking a long
21 time for me to download it.
22 MR. SLATER: Stop the timer.
23 Q. Would you like to read the
24 document? It is over 300 pages long, and I'm

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1 going to ask you about one sentence on
2 page 36. But if you'd like to read the whole
3 thing, we can stop and give you time.
4 A. I finished downloading, and I'm
5 on page 36 now.
6 MR. SLATER: Okay. We can
7 start the clock again.
8 Let's go to page 36, please,
9 Chris. Perfect.
10 Q. Looking at page 36 --
11 MR. SLATER: Can you make this
12 a little bigger, Chris? I'm sorry.
13 Perfect.
14 Q. Looking now at page 36, the
15 third paragraph starts, "It has been known
16 since 1865 that the reaction of dimethylamine
17 hydrochlorothiazide with sodium nitrite at an
18 acidic pH yields N-nitrosodimethylamine,"
19 which is NDMA.
20 So that's been known since
21 1865, yet ZHP's technical people couldn't
22 figure that out in 2011, correct?
23 MS. PRISELAC: Objection to
24 form. Lack of foundation. The

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1 document speaks for itself.
2 You can answer.
3 A. Well, I don't work on the
4 technical work. Based on this document, my
5 personal speculation here is that amine
6 reacts with nitroso agents to form NDMA.
7 MR. SLATER: Let's take that
8 document down and put up that
9 PowerPoint slide that you have, Chris,
10 when you get a second.
11 (Whereupon, Exhibit Number
12 ZHP-342 was marked for
13 identification.)
14 BY MR. SLATER:
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 MS. PRISELAC: Objection to
2 form. Lack of foundation, misstates
3 the prior testimony, and misstates the
4 evidence. The e-mail -- the e-mail
5 speak for itself.
6 MR. SLATER: I'm going to reask
7 the question. I'm withdrawing the
8 question, so I'm going to ask it again
9 differently.
10 BY MR. SLATER:
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 MS. PRISELAC: Objection to
20 form. Misstates the prior testimony.
21 Lack of foundation. The July 27, 2017
22 e-mail speaks for itself.
23 And she can answer if she can.
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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■ [REDACTED]

6 MS. PRISELAC: Adam, are you
7 trying to admit this PowerPoint as an
8 exhibit? What is this?
9 MR. SLATER: It's an exhibit
10 I'm using during the deposition. It's
11 Exhibit 342.
12 MS. PRISELAC: What is it?
13 It's a PowerPoint you created?
14 MR. SLATER: I didn't do it.
15 MS. PRISELAC: What is it?
16 MR. SLATER: Let's go off the
17 timer while we have this conversation.
18 MS. PRISELAC: No, we don't
19 need to.
20 MR. SLATER: Well, we are.
21 But I'm not sure -- I wouldn't
22 know how to create a PowerPoint.
23 Something else did, who is much more
24 savvy than me. We thought it was

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1 pretty good. It looks good, right?
2 MS. PRISELAC: I don't
3 understand what it is, though. I'm
4 asking for a proffer. What is this?
5 MR. SLATER: I asked a
6 question. I used that as part of the
7 foundation for the question. It's a
8 demonstrative exhibit.
9 MS. PRISELAC: Well, I'm
10 objecting to the use of this.
11 Okay. Go ahead, finish.
12 MR. SLATER: I do it a lot, but
13 who knows, I could be wrong.
14 MS. PRISELAC: I'm objecting to
15 the use of this. And anyway, I'm also
16 objecting to the content as
17 misleading, mischaracterizes the
18 evidence, and, you know, misstates --
19 and, I'm sorry, lack of foundation.
20 So please go ahead.
21 MR. SLATER: Go back on the
22 clock.
23 BY MR. SLATER:
24 ■ [REDACTED]

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■ [REDACTED]

7 MS. PRISELAC: Objection.
8 Misstates the prior testimony, lack of
9 foundation, ambiguous.
10 You can answer.
■ [REDACTED]

21 MS. PRISELAC: Adam, if you're
22 not going to ask about what's on the
23 slide, then you need to take it down.
24 I know you're trying to harass the

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1 witness.
2 MR. SLATER: You know, I'm
3 really not. I don't --
4 MS. PRISELAC: Then why are you
5 using it? I'm asking for a proffer.
6 MR. SLATER: You're not letting
7 me talk. I'm sorry.
8 I'm questioning the witness
9 about the content of this e-mail.
10 That is what this line of questions is
11 about.
12 MS. PRISELAC: Okay. But you
13 don't have the e-mail up. Where is
14 the e-mail?
15 MR. SLATER: You just stopped
16 me again.
17 I believe this is an
18 appropriate demonstrative tool to use
19 in a deposition. I'm going to proceed
20 now.
21 MS. PRISELAC: It is absolutely
22 inappropriate when you have the actual
23 e-mail, and so I'm asking that you
24 take it down now.

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1 MR. SLATER: I'm not going to.
2 MS. PRISELAC: It's misleading,
3 intimidating, and harassing. You have
4 the e-mail. Put up the e-mail if you
5 want to show it to her.
6 MR. SLATER: I appreciate your
7 position. I'm going to continue the
8 deposition now.
9 MS. PRISELAC: I'm going to ask
10 you again to take it down.
11 MR. SLATER: Let's go off the
12 clock. Please go off the clock.
13 Now you can say whatever you
14 want. I just was afraid we were
15 eating up time with your discussion.
16 MS. PRISELAC: Why would this
17 be more appropriate than the actual
18 e-mail, which is the best evidence?
19 This is a misleading summary.
20 MR. SLATER: I don't believe
21 so, and it's something I do all the
22 time in my deposition --
23 MS. PRISELAC: It doesn't mean
24 it's right.

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1 MR. SLATER: I know that it's
2 late. You're interrupting me, though,
3 so it's hard for me to state my
4 position.
5 MS. PRISELAC: Keep going.
6 MR. SLATER: No, I'm just
7 saying I think it's totally
8 appropriate to use a demonstrative
9 exhibit. Under these circumstances I
10 don't think it's misleading, and I'd
11 like to continue the deposition.
12 MS. PRISELAC: How is it a
13 demonstrative exhibit if you're trying
14 to show the contents of an e-mail and
15 you have the actual e-mail?
16 MR. SLATER: This is what we do
17 as lawyers all the time in these
18 cases.
19 MS. PRISELAC: No, it's not
20 true. I hate when you say that. Give
21 me a rule. Give me the law. I gave
22 you the law.
23 MR. SLATER: I'm not going to
24 argue the rules of evidence with you.

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1 It's appropriate to use.
2 MS. PRISELAC: I think you have
3 to give me one, though.
4 MR. SLATER: I don't have to
5 give you anything. I need to continue
6 the deposition. I'm confident this is
7 appropriate.
8 There will be -- at the time
9 that we designate testimony for trial,
10 you'll have your objections and the
11 Court will rule. I understand that.
12 I just would like to continue
13 the deposition now, if I could,
14 please.
15 MS. PRISELAC: No, because it's
16 harassing to the witness and an
17 attempt to intimidate her. So take it
18 down.
19 MR. SLATER: So you're not
20 going to let the deposition continue?
21 Look, I don't appreciate how
22 you're talking to me, with all due
23 respect. Telling me to take it down I
24 don't think is appropriate.

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1 I'm going to continue the
2 deposition. I'm very comfortable that
3 what I'm doing is appropriate. This
4 is the basis for this line of
5 questioning that your witness brought
6 us into with many statements she made.
7 This is now questioning her on
8 her testimony, and I think I can
9 proceed.
10 So I'd really appreciate it if
11 we could go back on the clock and if I
12 could continue with these substantive
13 questions, please.
14 MS. PRISELAC: So are you
15 telling me now on the record you are
16 refusing -- let me make it clear --
17 you are refusing to put up the actual
18 e-mail, and instead are relying on --
19 only put up a slide made by you or
20 someone in your office to -- instead
21 of the actual e-mail in a line of
22 questioning that's about e-mail, even
23 though you have the e-mail?
24 Is that your position?

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1 MR. SLATER: I mean, you can
2 characterize it any way you want. I'm
3 using this PowerPoint slide for the
4 time being. It's more efficient. I
5 believe it's not misleading in any
6 way, and I'd like to continue, if I
7 could, please.
8 MS. PRISELAC: You're using it
9 for what purpose exactly?
10 MR. SLATER: I'm using it as a
11 demonstrative exhibit to help to
12 facilitate testimony of the deponent.
13 MS. PRISELAC: Okay. A
14 demonstrative exhibit. Demonstrating
15 what?
16 MR. SLATER: Honestly, with all
17 due respect, I'm done with this
18 question-and-answer. I feel that I
19 don't need to go further. I've given
20 as much information --
21 MS. PRISELAC: I'm entitled to
22 ask of a demonstrative what are you
23 attempting to demonstrate? Because I
24 believe the answer is the contents of

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1 the e-mail, which makes it an
2 inappropriate demonstrative.
3 MR. SLATER: Okay. Well, then
4 we have a disagreement on the --
5 MS. PRISELAC: But I'd like to
6 get on the record for the judge what
7 you're trying to demonstrate.
8 MR. SLATER: This is all on the
9 record.
10 MS. PRISELAC: So tell me now
11 what you're trying to demonstrate
12 through this slide so it's on the
13 record, and we can take it up with the
14 judge.
15 MR. SLATER: A portion of the
16 substantive content of the e-mail
17 that's directly relevant to the
18 question.
19 I'm not sure why you're
20 laughing. I don't know why it's funny
21 to you.
22 MS. PRISELAC: Okay. Okay,
23 great. I have the perfect answer
24 because it proves my point, so we'll

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1 take it up with the judge.
2 I'm going to tell Ms. Lin that
3 she should disregard and not look
4 whatsoever at this PowerPoint. She
5 can answer your questions.
6 MR. SLATER: I guess you can
7 tell your client whatever you want. I
8 mean, I wouldn't stop you from telling
9 you her anything. I don't have the
10 right to do that.
11 MS. PRISELAC: Okay. So we can
12 go back on the timer and back on the
13 record -- I mean, we're on the record,
14 but we can go back on the timer.
15 And, Ms. Garland, please direct
16 Ms. Lin not to look at this
17 PowerPoint, and to only listen to
18 Mr. Slater's questions.
19 MR. SLATER: You don't need to
20 translate it. Your client is nodding.
21 She understood everything you just
22 said.
23 MS. PRISELAC: No, absolutely
24 not, Adam. And if you want to cast

Page 185

1 aspersions again --
2 MR. SLATER: Then go off the
3 clock again. Don't start the clock
4 again.
5 MS. PRISELAC: If you want to
6 cast aspersions about her language
7 abilities, that's fine. But I'm
8 asking Ms. Garland to translate that
9 because she does not understand
10 English well.
11 MR. SLATER: I'm sorry, that's
12 not an aspersion when I say somebody
13 understood. I think it would be the
14 opposite. I saw Ms. Lin nodding along
15 with you, so I assumed she understood
16 what you were saying. It wasn't an
17 aspersion.
18 MS. PRISELAC: Well, she didn't
19 say anything.
20 MR. SLATER: We're off the
21 clock, so we can go back and forth all
22 you want. I just want to try to
23 continue the deposition as I can.
24 MS. PRISELAC: Well, and I want

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1 to make a record about your conduct
2 and your inappropriate exhibit, so...
3 MR. SLATER: You know, you've
4 said this a lot of times about me to
5 try to create an impression about me.
6 I don't appreciate it.
7 MS. PRISELAC: You're using an
8 inappropriate, harassing PowerPoint.
9 I think that's the first time this has
10 come up, Adam.
11 So, okay, Ms. Garland, if you
12 could please translate for the witness
13 that she should not view this
14 PowerPoint, and she should only listen
15 to your translation of Mr. Slater's
16 questions when she's answering
17 questions. So thank you.
18 There's no pending question.
19 MR. SLATER: I'm sorry,
20 Maureen, I can't remember what
21 happened before the colloquy, whether
22 I asked a question and there was no
23 answer or if an answer was given.
24 Can you tell me and read to me

Page 187

1 the last thing that happened? I'd
2 appreciate that.
3 Oh, actually, you know what,
4 I'm going to save you the work. I
5 just checked my notes and I
6 remembered. Sorry about that,
7 Maureen.
8 Okay. So we're on the clock
9 now. We can go back on. I'm going to
10 continue the questioning now.
11 BY MR. SLATER:
12 Q. You testified that the --
13 rephrase.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 MS. PRISELAC: Objection.
23 Foundation, misstates the prior
24 testimony, ambiguous.

Page 188

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 MS. PRISELAC: Objection to
24 form. Lack of foundation.

Page 189

1 You can answer if you can.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MS. PRISELAC: Is that a

[illegible]

Page 191

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10 MS. PRISELAC: Objection to
11 form. Ambiguous, lack of foundation.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21 MS. PRISELAC: Objection to
22 form. Lack of foundation.
23 She can answer if she's able.

[REDACTED]

[REDACTED]

[REDACTED]

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1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
6 MS. PRISELAC: Objection to
7 form.
8 Is that a question.
9 MR. SLATER: She asked me, so I
10 was answering. I'll answer it
11 differently. I'll start it over.
12 BY MR. SLATER:
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
17 MS. PRISELAC: Objection to
18 form. Lack of foundation, ambiguous.
19 She can answer if she's able.
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Page 193

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12 MS. PRISELAC: Objection to

13 form. Compound, ambiguous,

14 argumentative.

15 MR. SLATER: I'll reask the

16 question differently.

17 BY MR. SLATER:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

23 MS. PRISELAC: Objection to

24 form. Compound, ambiguous,

Page 194

1 argumentative.
2 She can answer if she's able.
3 A. Well, this is a long question.
4 I did not hear it very clearly, and it sounds
5 like it involves several questions. Could
6 you break it down to single questions?
7 BY MR. SLATER:
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 Is that your testimony?
17 MS. PRISELAC: Objection to
18 form. Compound, ambiguous, misstates
19 the prior testimony.
20 She can answer if she's able.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 195

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED].
6 MS. PRISELAC: Adam, we've been
7 going like over an hour and a half.
8 Do you want to take a break? I'd like
9 to ask you to take a break.
10 MR. SLATER: I'd like to go
11 just a couple more minutes, and then
12 we'll hit a good break point.
13 MS. PRISELAC: That's fine with
14 me if it's okay with the translator
15 and the witness.
16 THE INTERPRETER: It's okay
17 with me.
18 And would you like me to check
19 with the witness?
20 MS. PRISELAC: Yes.
21 A. I'll do whatever my attorney
22 tells me to do.
23 MS. PRISELAC: Okay. Well,
24 then let's just -- five more minutes,

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1 Adam, that's fine.
2 MR. SLATER: Sure.
3 BY MR. SLATER:
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 MS. PRISELAC: Objection to
15 form. Misstates the evidence, lack of
16 foundation, compound.
17 She can answer if she's able.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 197

1 [REDACTED]
2 BY MR. SLATER:
3 Q. Can you please answer my
4 question?
5 MS. PRISELAC: Objection to
6 form.
7 BY MR. SLATER:
8 Q. I'll ask it again.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MS. PRISELAC: Objection to
17 form. Objection to the use of
18 Exhibit 342 rather than the actual
19 e-mail. Mischaracterizes the
20 evidence. Mischaracterizes the actual
21 exhibit. Lack of foundation,
22 ambiguous, asked and answered.
23 [REDACTED]
24 [REDACTED]

Page 198

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 BY MR. SLATER:
10 Q. Can you please answer my
11 question?
12 MS. PRISELAC: Adam, we're way
13 past five minutes now, so can we take
14 a break?
15 MR. SLATER: I realize that,
16 I'm just -- we can take a break.
17 MS. PRISELAC: You can ask her
18 when we come back.
19 MR. SLATER: It's fine. We can
20 break. Let's go off the record.
21 THE VIDEOGRAPHER: The time
22 right now is 10:12 a.m. We're now off
23 the record.
24 ///

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1 (Whereupon, a recess was
2 taken.)
3 THE VIDEOGRAPHER: The time
4 right now is 10:32 a.m. We're back on
5 the record.
6 BY MR. SLATER:
7 Q. On the screen is Exhibit 213,
8 which is a November 29, 2018 Warning Letter
9 from the FDA to ZHP.
10 You're familiar with that
11 document, right?
12 A. I am aware of the existence of
13 this document. But am I familiar with it?
14 It's been a long time, so I can't say that
15 now I'm very familiar with this document.
16 Q. On the screen we have
17 Exhibit 213, a November 29, 2018 Warning
18 Letter from the FDA to ZHP.
19 Do you see that on the screen?
20 MS. PRISELAC: I just want
21 to -- could somebody upload it to the
22 website? Because it's not here.
23 A. I see this document.
24 ///

Page 200

1 BY MR. SLATER:
2 Q. The first paragraph says the
3 FDA inspected ZHP's manufacturing facility
4 July 23 to August 3, 2018.
5 That was after ZHP disclosed
6 the NDMA in its valsartan, correct?
7 MS. PRISELAC: Objection to
8 form. The document speaks for itself.
9 A. Yes, that is what is said on
10 this document.
11 BY MR. SLATER:
12 Q. The second paragraph says,
13 "This warning letter summarizes significant
14 deviations from current good manufacturing
15 practice (CGMP) for active pharmaceutical
16 ingredients (API)." Correct?
17 MS. PRISELAC: Objection to
18 form. The document speaks for itself.
19 A. Yes, that is how it's described
20 here in this document.
21 MR. SLATER: Scroll up a little
22 bit, Chris, please. Perfect.
23 BY MR. SLATER:
24 Q. The third paragraph states,

Page 201

1 "Because your methods, facilities, or
2 controls for manufacturing, processing,
3 packing, or holding do not conform to CGMP,
4 your API are adulterated within the meaning
5 of Section 501(a)(2)(B) of the Federal Food,
6 Drug, and Cosmetic Act, 21 USC 351(a)(2)(B)."
7 Do you understand what
8 "adulterated" means?
9 MS. PRISELAC: Objection to
10 form. The document speaks for itself.
11 Lack of foundation.
12 A. Based on my personal
13 understanding, this is a boilerplate sentence
14 that appears in all warning letters from the
15 FDA. All of our manufacturing conforms to
16 GMP.
17 BY MR. SLATER:
18 Q. Please answer my question. I
19 asked if you understood what "adulterated"
20 means as used in that sentence.
21 MS. PRISELAC: Objection to
22 form. Asked and answered,
23 argumentative. My prior objection
24 also stands.

<p style="text-align: right;">Page 202</p> <p>1 A. My answer is that this sentence 2 appears in all FDA warning letters. 3 I would like to emphasize here 4 that the manufacturing of API by ZHP is in 5 compliance with our quality system, and it is 6 in compliance with GMP. 7 BY MR. SLATER: 8 Q. Can you please answer my 9 question? What is your understanding of what 10 "adulterated" means as used in that sentence? 11 MS. PRISELAC: Objection to 12 form. Asked and answered. My prior 13 objection stands also. 14 A. My answer is that in this 15 entire sentence, my personal understanding is 16 that it appears in all warning letters from 17 the FDA, and this sentence comes from this 18 regulation here. 19 BY MR. SLATER: 20 Q. Are you refusing to tell me 21 your understanding of what the word 22 "adulterated" means as used in that sentence? 23 Because that's my question. 24 MS. PRISELAC: Objection to</p>	<p style="text-align: right;">Page 204</p> <p>1 MS. PRISELAC: Objection to 2 form. Calls for a legal conclusion, 3 ambiguous. 4 She can answer if she's able. 5 A. Well, for the meaning of this 6 word, we need to look at the regulation. My 7 understanding is that the manufacturing and 8 control of our APIs are all in compliance 9 with what is stated in our filed documents 10 and in compliance with cGMP. 11 BY MR. SLATER: 12 Q. You are the director of 13 regulatory affairs for all of ZHP. Do you 14 know what "adulterated" means as defined in 15 the laws that are cited there in the letter, 16 or don't you know? 17 MS. PRISELAC: Asked and 18 answered. 19 She can answer if she's able. 20 A. The meaning of this word should 21 be defined in the law. 22 As of now, my understanding is 23 that the manufacturing of our valsartan -- 24 excuse me.</p>
<p style="text-align: right;">Page 203</p> <p>1 form. Asked and answered, 2 argumentative. 3 She can answer if she's able. 4 A. Well, the meaning of this word 5 in the whole sentence must be put in the 6 context of this entire sentence. And based 7 on what I know, this sentence is a 8 boilerplate of the FDA. 9 BY MR. SLATER: 10 Q. What does "adulterated" mean as 11 used in that sentence? 12 MS. PRISELAC: Objection to 13 form. Asked and answered. 14 She can answer if she's able. 15 A. All of our manufacturing 16 follows cGMP requirements and conditions. We 17 believe that our API meets applicable 18 standards, and this sentence, according to 19 what I know, is really a boilerplate 20 sentence. 21 BY MR. SLATER: 22 Q. Do you know what the word 23 "adulterated" means as used in the federal 24 regulations in the United States?</p>	<p style="text-align: right;">Page 205</p> <p>1 The manufacturing of our 2 valsartan API was in compliance with cGMP, 3 and our products did not have these problems. 4 BY MR. SLATER: 5 Q. Do you not know the definition 6 of "adulterated," the regulatory definition 7 as used in that sentence, or do you? 8 MS. PRISELAC: Objection to 9 form. Asked and answered. 10 BY MR. SLATER: 11 Q. I'll ask it again. New 12 question. 13 What is the definition of 14 "adulterated"? 15 A. What I want to say is this 16 paragraph is in a warning letter from the 17 FDA. In this letter, the source of this word 18 is cited, so the meaning of this word can be 19 found, or should be found, in the document 20 cited here. 21 Based on my current knowledge, 22 our products are manufactured and tested in 23 accordance with cGMP and GMP system. Our 24 entire system is in compliance with GMP.</p>

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1 MR. SLATER: Let's go to page 4
2 of this letter.
3 Q. This letter lists the
4 deviations that were found by the
5 investigators, and this is deviation number
6 2, "Failure to evaluate the potential effect
7 that changes in the manufacturing process may
8 have on the quality of your API."
9 That was deviation number 2
10 identified by the FDA investigators, correct?
11 MS. PRISELAC: Objection to
12 form. The document speaks for itself.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 BY MR. SLATER:
22 Q. All I asked you is if number 2
23 is the second deviation identified by the
24 investigators according to this letter.

Page 207

1 Is it?
2 A. That is how it is stated in
3 this document. However, we had objection to
4 the deviation.
5 Q. Under the heading number 2, the
6 FDA writes, "In November 2011 you approved a
7 valsartan API process change (PCRC - 11025)
8 that included the use of the solvent DMF."
9 That's referring to the process
10 change to use the zinc chloride process,
11 right?
12 A. Yes.
13 Q. The paragraph continues, "Your
14 intention was to improve the manufacturing
15 process, increase product yield, and lower
16 production costs."
17 The focus on increasing the
18 yield and lowering the cost was important for
19 ZHP in instituting the zinc chloride process,
20 right?
21 MS. PRISELAC: Objection to
22 form. The document speaks for itself,
23 lack of foundation.
24 [REDACTED]

Page 208

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 BY MR. SLATER:
12 Q. All right. Let's jump to
13 Exhibit 312, and then we'll come back to
14 this.
15 Exhibit 312 is the
16 Establishment Inspection Report that the FDA
17 served on ZHP regarding that inspection from
18 July 23, 2018 to August 3, 2018, the same
19 inspection discussed in Exhibit 213, correct?
20 A. Exhibit 213, is it the document
21 we just reviewed?
22 Q. Right, the FDA Warning Letter
23 from November 2018.
24 A. That was of the same

Page 209

1 inspection.
2 MR. SLATER: Chris, go to
3 page 25 of 58. The numbers are at the
4 bottom of the pages, please. Thank
5 you.
6 Q. Looking at the paragraph at the
7 center of the page, this report discusses
8 a -- rephrase.
9 Looking at the paragraph in the
10 center of the page, the investigator reports
11 a discussion wherein "Mr. Jun Du, Executive
12 Vice President...stated the change control
13 should have stated the purpose of the change
14 was to save money. Mr. Du further stated the
15 cost reduction was so significant it is what
16 made it possible for the firm to dominate the
17 world market share."
18 Do you see what I just read,
19 documenting what Jun Du told the FDA the
20 purpose of the process change was?
21 A. Well, I see that in this
22 document it says so, but in my recollection I
23 do not recall Mr. Du saying this to the FDA.
24 This is not what I can recall.

Page 210

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 Q. Are you saying Jun Du didn't
7 know what he was talking about?
8 MS. PRISELAC: Objection to
9 form. Argumentative.
10 A. I said in my recollection, I do
11 not recall him saying that to the FDA.
12 Throughout the inspection I was not always
13 with Mr. Du Jun, so what I'm saying is that I
14 personally do not recall him saying that.
15 BY MR. SLATER:
16 Q. Jun Du -- rephrase.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MS. PRISELAC: Objection to

Page 211

1 form. Compound, misstates the prior
2 testimony.
3 You can answer if you're able.
4 MR. SLATER: Actually, I'm
5 going to withdraw the question,
6 because there was so many objections
7 I'm going to reask the question.
8 MS. PRISELAC: There were only
9 objections because you asked about
10 three questions in one question, among
11 my other objections.
12 BY MR. SLATER:
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MS. PRISELAC: Objection. Lack
19 of foundation, misstates the prior
20 testimony.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 212

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MS. PRISELAC: Objection to
13 form. Misstates the prior testimony.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 213

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 MS. PRISELAC: Objection to
16 form.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 214

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 MS. PRISELAC: Objection to
11 form.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 215

1 [REDACTED]
2 [REDACTED]
3 MS. PRISELAC: Objection to
4 form. Misstates the prior testimony,
5 compound.
6 She can answer if she's able.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MR. SLATER: Let's go back to
19 Exhibit 213 where we left off, please.
20 Impressive.
21 BY MR. SLATER:
22 Q. Going back now to the
23 November 29, 2018 warning letter, the
24 paragraph under number 2, the FDA pointed out

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1 starting in the third sentence on the third
2 line, "However, you failed to adequately
3 assess the potential formation of mutagenic
4 impurities when you implemented the new
5 process. Specifically, you did not consider
6 the potential for mutagenic or other toxic
7 impurities to form from DMF degradants,
8 including the primary DMF degradant,
9 dimethylamine."
10 That's a true statement
11 regarding a failing in the risk assessment
12 performed by ZHP, correct?
13 MS. PRISELAC: Objection to
14 form. The document speaks for itself,
15 ambiguous.
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 217

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 BY MR. SLATER:
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 218

1 [REDACTED]

2 MS. PRISELAC: Objection to

3 form.

4 Do you want to --

5 MR. SLATER: I'm going to reask

6 it, actually. I'll ask another

7 question.

8 MS. PRISELAC: Okay.

9 MR. SLATER: I'm going to have

10 to ask a new question.

11 BY MR. SLATER:

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 MS. PRISELAC: Objection to

20 form.

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 219

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 MS. PRISELAC: Objection to

24 form. Misstates the prior testimony,

Page 220

1 asked and answered.

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 BY MR. SLATER:

8 Q. Do you recall the scientific

9 literature I showed you earlier that

10 specifically said that DMF could degrade and

11 yield dimethylamine?

12 MS. PRISELAC: Objection to

13 form. Misstates the evidence.

14 A. Before, we did not have any

15 knowledge that DMF was not stable and could

16 degrade to DMA. I personally did not have

17 that knowledge, and no one told me about it.

18 At ZHP, no one mentioned that

19 they were aware of this particular

20 literature. It was only when Mr. Slater

21 showed me this document that I saw it for the

22 first time.

23 MS. PRISELAC: Adam, I think

24 we've been going like 70 minutes. Can

Page 221

1 we take a break?

2 MR. SLATER: Sure. Let's go

3 off the record.

4 THE VIDEOGRAPHER: The time

5 right now is 11:45 a.m. We're now off

6 the record.

7 (Whereupon, a recess was

8 taken.)

9 THE VIDEOGRAPHER: The time

10 right now is 11:56 a.m. We're back on

11 the record.

12 MR. SLATER: Can we get that

13 document back up, Chris? Thanks.

14 BY MR. SLATER:

15 Q. Looking at the second paragraph

16 under number 2, the FDA stated, "You also

17 failed to evaluate the need for additional

18 analytical methods to ensure that

19 unanticipated impurities were appropriately

20 detected and controlled in your valsartan API

21 before you approved the process change."

22 That's certainly one of the

23 reasons why ZHP did not know there was NDMA

24 in its valsartan when it developed the zinc

Page 222

1 chloride process, right?

2 MS. PRISELAC: Objection to

3 form. Lack of foundation.

4 A. Personally, I'm not sure why

5 this is written here. As according to my

6 knowledge, we had already developed methods

7 and tested for all impurities that we could

8 think of back then. In 2012, these were all

9 listed in the document that we submitted to

10 the FDA.

11 BY MR. SLATER:

12 Q. In the second paragraph under

13 deviation number 2, the second sentence says,

14 "You are responsible for developing and using

15 suitable methods to detect impurities when

16 developing, and making changes to, your

17 manufacturing processes. If new or higher

18 levels of impurities are detected, you should

19 fully evaluate the impurities and take action

20 to ensure the drug is safe for patients."

21 In terms of detecting

22 impurities as discussed there, ZHP failed to

23 detect the NDMA impurity when it developed

24 the zinc chloride process, right?

Page 223

1 MS. PRISELAC: Objection to

2 form. Vague.

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 BY MR. SLATER:

19 Q. Whatever ZHP did failed to

20 detect NDMA as a potential impurity, failed

21 to identify it in the valsartan manufactured

22 with the zinc chloride process, correct?

23 MS. PRISELAC: Objection to

24 form. Compound, vague.

Page 224

1 BY MR. SLATER:

2 Q. I'll ask a new question.

3 Whatever ZHP did, it was a

4 failure in identifying NDMA as a potential

5 impurity because NDMA was not identified,

6 correct?

7 MS. PRISELAC: Objection.

8 Vague.

9 A. After June 2018, it was only

10 after then that we learned about the

11 existence of NDMA in our products. Before

12 that, we did not know about it. Therefore,

13 in 2012, for the evaluation in 2012, we

14 believe our evaluation was complete.

15 BY MR. SLATER:

16 Q. You were wrong, isn't that so?

17 MS. PRISELAC: Objection to

18 form. Vague.

19 BY MR. SLATER:

20 Q. Hang on, I'll ask it again.

21 You just said you thought your

22 evaluation was complete; but, in fact, you

23 were wrong, isn't that so?

24 A. Any evaluation is associated

Page 225

1 with a time period. The discovery of NDMA

2 depended on analytical method means for

3 discovery and the understanding of the

4 process, and these evolve over time. In

5 2012, when we started on the process change

6 involving zinc chloride, our risk assessment

7 at that time was adequate.

8 Q. Well, in fact, your risk

9 assessment was inadequate and failed to

10 identify the risk of NDMA forming. That's

11 the truth, isn't it?

12 MS. PRISELAC: Objection to

13 form. Argumentative, compound.

14 A. In 2012, based on our knowledge

15 level then, we believed that our evaluation

16 at that time was adequate, and that was the

17 basis for our approval of this change.

18 MR. SLATER: Chris, let's jump

19 to another document for a moment.

20 Let's go to Exhibit 310, please.

21 Thank you.

22 BY MR. SLATER:

23 Q. I'm showing you Exhibit 310.

24 That is the ICH M7 guideline from February of

Page 226

1 2013.
2 Do you see that?
3 A. I see it.
4 Q. The title is "Assessment and
5 Control of DNA Reactive (Mutagenic)
6 Impurities in Pharmaceuticals to Limit
7 Potential Carcinogenic Risk."
8 That's the title, right?
9 MS. PRISELAC: Objection. The
10 document speaks for itself.
11 A. This is the title of this
12 document.
13 MR. SLATER: Chris, please go
14 to page 10. Can we get it a little
15 bigger, please? I'm going to want the
16 top paragraph to start. Perfect.
17 BY MR. SLATER:
18 Q. Looking at the top of page 10
19 of the M7 guideline from 2013, it says, "A
20 disproportionally high number of members of
21 some structural classes of mutagens, i.e.,
22 aflatoxin like, N-nitroso-, and azoxy
23 structures, of which some may occur as
24 impurities in pharmaceuticals, display

Page 227

1 extremely high carcinogenic potency.
2 Acceptable intakes for these high-potency
3 carcinogens would likely be significantly
4 lower than the acceptable intakes defined in
5 this guideline."
6 An N-nitroso compound includes
7 NDMA, correct?
8 MS. PRISELAC: Objection to
9 form. The document speaks for itself.
10 She can answer if she is able.
11 A. This is what is written here in
12 this document. [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 228

1 [REDACTED]
2 [REDACTED]
3 MR. SLATER: Let's scroll down,
4 Chris, to the second paragraph after
5 Section 8. A little more. Perfect.
6 BY MR. SLATER:
7 Q. Looking now at Section 8 under
8 the heading "Control," after the bullet
9 points it says, "When an impurity has been
10 characterized as mutagenic, it is important
11 to develop a control strategy that assures
12 that the level of this impurity in the drug
13 substance and drug product is below the
14 acceptable limit. A thorough knowledge of
15 the chemistry associated with the drug
16 substance manufacturing process, the drug
17 product manufacturing process, along with an
18 understanding of the overall stability of the
19 drug substance and drug product is
20 fundamental to developing the appropriate
21 controls."
22 In the case of the zinc
23 chloride process, ZHP did not have a thorough
24 knowledge of the chemistry involved in that

Page 229

1 process, and that's why NDMA was not
2 considered or detected, correct?
3 MS. PRISELAC: Objection to
4 form. The document speaks for itself.
5 Lack of foundation.
6 Adam, can we at least get an
7 agreement now that you're well past
8 the 30(b)(6) topics?
9 MR. SLATER: No, we can't get
10 an agreement.
11 MS. PRISELAC: Okay. I want
12 to -- because, I mean, this is --
13 MR. SLATER: You know what, off
14 the timer. Go off the timer. If
15 we're going to get -- if I'm going to
16 get lectured, I'd rather not use my
17 time to be lectured.
18 MS. PRISELAC: Adam, let's just
19 make something clear. I'm allowed to
20 ask you what your basis is for you
21 considering anything in this document
22 as part of a 30(b)(6) topic. I have
23 my standing objection, and it does
24 stand.

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But you're on now to documents that have nothing to do with a regulatory authority. So tell me, I am entitled to know, how you think this fits into any of her topics.

MR. SLATER:

So I think it's appropriate for both reasons. I'm ready to continue any time.

MS. PRISELAC: Okay. So this

MR. SLATER: Chris, let's go back to Exhibit 213, please.

Q. Looking now at the third paragraph under heading number 2, the FDA said, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra

has nothing to do with her topics, so I'm glad we got that clear.

Back on the timer. Let's move on.

MR. SLATER: I thought that we were going to try to minimize these kinds of comments. I'd really appreciate it if you'd just move along with the deposition.

MS. PRISELAC: I'm absolutely entitled to know what your basis for claiming these are in the topics.

But it's not on the timer and you're not prejudiced in any way, so let's just move on.

MR. SLATER: Is it okay for me to continue now?

MS. PRISELAC: What I just said, Adam.

MR. SLATER: Let's go back on the timer.

BY MR. SLATER:

Q. Answer the question, please.

dimension over current industry practice, and that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce."

So, therefore, the FDA specifically rejected the argument that you just made in the answer to the last question, correct?

MS. PRISELAC: Objection to form. Lack of foundation, misstates the evidence. You can -- and this document speaks for itself.

You can answer the question if you're able.

A. Here in this report, I personally believe that it is the personal opinion of the inspector. After this event, there were FDA documents discussing FDA's opinion about the discovery of NDMA.

In 2012 when this change was proposed, we did perform evaluation on the

Page 234

1 change strictly in accordance with cGMP;
2 therefore, personally I believe that we were
3 in compliance with cGMP requirements.
4 MR. SLATER: Chris, let's go to
5 page 6 of this letter, the last page,
6 please.
7 BY MR. SLATER:
8 Q. Starting from the bottom.
9 Let's look at the bottom.
10 This letter was signed by
11 someone named "Francis Godwin, the Acting
12 Director of the Office of Manufacturing
13 Quality, Office of Compliance, Center for
14 Drug Evaluation and Research" at the FDA,
15 correct?
16 MS. PRISELAC: Objection to
17 form. The document speaks for itself.
18 A. This is what is written here in
19 this document.
20 I would like to make a
21 clarifying correction. When I said
22 "inspector" earlier, for us all FDA officials
23 are inspectors.
24 MR. SLATER: Let's go to the

Page 235

1 top of the page, Chris. Perfect.
2 BY MR. SLATER:
3 Q. Looking at the top of the
4 page 6, this first full paragraph, which is
5 just one line, says, "FDA" -- rephrase.
6 Looking at the top of page 6,
7 the FDA warned ZHP in this warning letter
8 that "FDA placed your firm on Import Alert
9 66-40 on September 28, 2018."
10 That import alert restricted
11 ZHP from selling drugs in the United States,
12 is that correct?
13 A. Based on my personal knowledge,
14 this import ban was specifically targeting
15 APIs manufactured in the Chuannan facility of
16 ZHP.
17 Q. Was the import alert ever
18 lifted?
19 A. This import ban has not been
20 lifted due to the pandemic last year. We
21 have been requesting the FDA to conduct
22 another inspection, but due to the pandemic
23 this second inspection never happened.
24 Q. Is ZHP currently selling any

Page 236

1 drugs into the United States?
2 A. This is a question I believe
3 that I cannot answer, because I am not a
4 salesperson.
5 MR. SLATER: Let's take that
6 document down.
7 Q. Ultimately -- rephrase.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MS. PRISELAC: Objection to
17 form. Compound, vague, misstates the
18 prior testimony.
19 She can answer if she is able.
20 A. Sorry, I wasn't focusing just
21 now. Could you state your question again?
22 MR. SLATER: I think it would
23 be for you, the translator, to just
24 read the question to her again, right?

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1 THE INTERPRETER: Interpreter
2 will interpret the question again.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MR. SLATER: Let's go to
19 Exhibit 212, please.
20 BY MR. SLATER:
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 238

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 MS. PRISELAC: Objection to
21 form. Lack of foundation, misstates
22 the prior testimony. Completeness, as
23 this appears to be a draft.
24 I would also state that other

Page 239

1 witnesses were specifically assigned
2 the topic of talking about
3 investigation and deviation reports
4 that are not Ms. Lin.
5 But she can go ahead and answer
6 in her personal capacity if she's
7 able.
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 MR. SLATER: Let's take this
23 document down and go to Exhibit 210.
24 ///

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1 BY MR. SLATER:
2 Q. On the screen is Exhibit 210,
3 "Deviation Investigation Report." It has a
4 date of November 5, 2018 as its preparation
5 date.
6 Do you see that?
7 A. I see it on the shared screen.
8 MR. SLATER: Chris, could you
9 go to page 12 of 236, please? Thank
10 you.
11 Q. It states in the middle of
12 Section 3 point -- rephrase.
13 Looking at the second paragraph
14 on page 12 it states, "Carcinogenicity
15 studies in animals demonstrated that NDMA is
16 carcinogenic. However, no evidence is
17 available to confirm that NDMA is
18 carcinogenic in humans. Nevertheless, NDMA
19 is considered a probable human carcinogen
20 based on projection from the animal studies."
21 And this is a report written by
22 ZHP, correct?
23 MS. PRISELAC: Objection to
24 form. The document speaks for itself.

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1 A. First, I did not write this
2 document. Strike that.
3 First, this is what is written
4 in this document.
5 Second, I did not write this
6 document, and I am not an expert on
7 toxicology. I do not know who wrote this
8 paragraph. What I do know is that NDMA is a
9 potential genotoxic impurity.
10 MR. SLATER: Go to the prior
11 page, Chris, please, page 11.
12 Perfect.
13 BY MR. SLATER:
14 Q. In the second paragraph on
15 page 11, there's a citation to an article
16 from the World Health Organization in 2002.
17 Do you see that?
18 MS. PRISELAC: Objection. The
19 document speaks for itself.
20 A. That is what's written here in
21 this paragraph.
22 MR. SLATER: Chris, let's go
23 back to the next page again, page 12.
24 Actually, you know what, let's

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1 just take this -- let's go to the
2 next. You can put that aside.
3 Let's go to the next exhibit,
4 which is Exhibit 321, which is the
5 article -- rephrase.
6 BY MR. SLATER:
7 Q. Looking now at the screen is
8 Exhibit 321, which is the article I just
9 identified in the ZHP Deviation Investigation
10 Report, Exhibit 210.
11 Do you see that in front of
12 you?
13 MS. PRISELAC: Objection to
14 form. Lack of foundation, outside the
15 scope of the 30(b)(6) topic.
16 She can answer if she's able.
17 A. I have not read this entire
18 document. And as I said, I'm not an expert
19 on toxicology; therefore, I cannot answer
20 these type of questions.
21 MR. SLATER: Chris, could you
22 go now to page 23, please, of this
23 article which is cited in the ZHP site
24 investigation report? Top of the

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1 page. Perfect.
2 MS. PRISELAC: Objection,
3 because I would also note that that
4 deviation investigation report is,
5 again, outside the scope of her
6 30(b)(6) topics.
7 MR. SLATER: You are aware it
8 was provided to the FDA, right?
9 MS. PRISELAC: Excuse me?
10 MR. SLATER: You are aware it
11 was provided to the FDA, right?
12 MS. PRISELAC: You're not
13 asking her -- are you going to ask her
14 that question, lay a foundation?
15 MR. SLATER: I'm going to
16 continue. You're eating my time. I'm
17 going to continue.
18 MS. PRISELAC: I'm allowed to
19 object to foundation. You're not
20 going to bully me out of it.
21 You're on the clock. Keep
22 going.
23 MR. SLATER: We can go back on
24 now.

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1 BY MR. SLATER:
2 Q. Looking now on page 23 of this
3 World Health Organization article from 2002,
4 in the top right of the column, it says,
5 "Therefore, owing to the considerable
6 evidence of carcinogenicity of NDMA in
7 laboratory species, evidence of direct
8 interaction with DNA consistent with tumour
9 formation, and the apparent lack of
10 qualitative species-specific differences in
11 the metabolism of this substance, NDMA is
12 highly likely to be carcinogenic to humans."
13 Do you see what I just read?
14 MS. PRISELAC: Objection to
15 form. The document speaks for itself.
16 She can answer if she's able.
17 A. I see this paragraph, but as I
18 said, I'm not an expert on toxicology;
19 therefore, I cannot comment on the content
20 here. I know that NDMA is a potential
21 genotoxic impurity.
22 MR. SLATER: Chris, let's go
23 back, if we could, to the deviation
24 investigation report, Exhibit 210,

Page 245

1 page 12.
2 MS. PRISELAC: Can I get an
3 official time on the record?
4 MR. SLATER: Go off the clock.
5 THE VIDEOGRAPHER: Five hours
6 and two minutes.
7 MS. PRISELAC: Okay. This is
8 your last question, Adam.
9 MR. SLATER: I would appreciate
10 some level of -- I don't know what to
11 even call it. I would like to finish.
12 I have a couple more questions.
13 MS. PRISELAC: Okay. Back on
14 the record.
15 MR. SLATER: Yeah, we'll go
16 back on. I have a couple more
17 questions.
18 And I don't think we're at
19 5:02, because there's been a lot of
20 times we've stopped the clock, and I
21 don't think it's been captured. So
22 I'm going to ask a couple more
23 questions --
24 MS. PRISELAC: Actually, it has

Page 246

1 been. I've been very on top of it, so
2 this is it.
3 MR. SLATER: I have about five
4 more minutes.
5 MS. PRISELAC: No, you don't.
6 And you have several more hours
7 and several more days, so this is your
8 last question.
9 MR. SLATER: In that case, go
10 to Exhibit 319, please, Chris. You've
11 got to blow it up.
12 BY MR. SLATER:
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 247

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 That information was not placed
9 into that deviation investigation report
10 which was provided to the FDA. Instead, you
11 had a sentence in there saying that there's
12 no evidence that NDMA is a human carcinogen,
13 correct?
14 MS. PRISELAC: Objection to
15 form. Lack of foundation,
16 completeness, hearsay, unable to know
17 whether it misstates the testimony
18 since you haven't laid a foundation
19 for it.
20 She can answer if she's able.
21 A. Well, I think there must have
22 been a context for their communication.
23 Without this context, I cannot answer this
24 question, because if I provide my personal

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1 speculation, it might be misleading.
2 MS. PRISELAC: Okay. That's
3 the end of the deposition. Let's go
4 off the record.
5 MR. SLATER: Well, we're not
6 going off the record because I'm going
7 to say something, but you can end the
8 deposition, but I'll certainly make it
9 clear that --
10 MS. PRISELAC: What are you
11 going to say?
12 MR. SLATER: I can't -- I don't
13 want to interrupt you. I didn't
14 realize you were talking again.
15 Can I speak, please?
16 MS. PRISELAC: Go for it, Adam.
17 MR. SLATER: I would like to be
18 able to continue for a few more
19 minutes and finish this line of
20 questioning. Defense counsel has
21 determined to stop the deposition
22 tonight and preclude me from asking
23 any further questions.
24 I wish that I was able to

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1 finish this line of questions, but
2 I've been told by defense counsel I
3 cannot, and defense counsel
4 unilaterally ended the deposition for
5 tonight.
6 MS. PRISELAC: I'm ending the
7 deposition because it is over four
8 hours and 1:15 in the morning, which
9 is well within the rules of the
10 protocol. And this witness has
11 several more hours and two entire more
12 days of deposition testimony, so you
13 can continue your questioning,
14 Mr. Slater, tomorrow, and that will
15 not prejudice you in any way.
16 So good evening, and have a
17 good night.
18 MR. SLATER: Thank you.
19 Thanks, everybody.
20 Thank you, Maureen. Thank you,
21 team. Really enjoyed it tonight.
22 THE VIDEOGRAPHER: The time
23 right now is 1:15 p.m. We are now off
24 the record.

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1 (Whereupon, the deposition was
 2 adjourned.)
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1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it. It will be
 10 attached to your deposition.
 11 It is imperative that you return
 12 the original errata sheet to the deposing
 13 attorney within thirty (30) days of receipt
 14 of the deposition transcript by you. If you
 15 fail to do so, the deposition transcript may
 16 be deemed to be accurate and may be used in
 17 court.
 18
 19
 20
 21
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 23
 24

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1 CERTIFICATE
 2
 3 I, MAUREEN O'CONNOR
 4 POLLARD, Registered Diplomat
 5 Reporter, Realtime Systems
 6 Administrator, and Certified Shorthand
 7 Reporter, do hereby certify that prior
 8 to the commencement of the
 9 examination, LIHONG (LINDA) LIN, was
 10 remotely duly identified and sworn by
 11 me to testify to the truth, the whole
 12 truth, and nothing but the truth.
 13 I DO FURTHER CERTIFY that
 14 the foregoing is a verbatim transcript
 15 of the testimony as taken
 16 stenographically by and before me at
 17 the time, place, and on the date
 18 hereinbefore set forth, to the best of
 19 my ability.
 20 I DO FURTHER CERTIFY that
 21 I am neither a relative nor employee
 22 nor attorney nor counsel of any of the
 23 parties to this action, and that I am
 24 neither a relative nor employee of
 such attorney or counsel, and that I
 am not financially interested in the
 action.

 MAUREEN O'CONNOR POLLARD
 NCRA Registered Diplomat Reporter
 Realtime Systems Administrator
 Certified Shorthand Reporter
 Notary Public
 Dated: May 10, 2021

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 2 E R R A T A
 3 -----
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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
Hereby certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

Lihong (Linda) Lin Date

Subscribed and sworn
To before me this
_____ day of _____, 20____.

My commission expires: _____

Notary Public

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LAWYER'S NOTES

PAGE LINE

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Exhibit 95

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 - - - - -

5 IN RE: VALSARTAN, MDL NO. 2875
6 LOSARTAN, AND
7 IRBESARTAN PRODUCTS CIVIL ACTION NO.
8 LIABILITY LITIGATION 19-2875
9 (RBK/JS)

10 - - - - -

11 THIS DOCUMENT APPLIES HONORABLE
12 TO ALL CASES ROBERT B. KUGLER
13 - CONFIDENTIAL INFORMATION -
14 SUBJECT TO PROTECTIVE ORDER

15 - - - - -

16 Thursday, May 13, 2021

17 - - - - -

18 Videotaped remote deposition of DAWN
19 CHITTY, taken pursuant to notice, was held via Zoom
20 Videoconference, commencing at 9:07 a.m., by and
21 before Robin L. Clark, Registered Professional
22 Reporter and Notary Public.

23 - - - - -

24

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1 I N D E X
2 WITNESS PAGE
3 DAWN CHITTY
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4 BY MS. PAPANTONIO: 185
BY MS. NAGLE: 435
5
6 E X H I B I T S
7 NUMBER DESCRIPTION MARKED
8 Torrent
9 Exhibit 77 Interim Limits for NDMA, 23
NDEA, and NMBA in
10 Angiotensin II Receptor
Blockers (ARBs)
11
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<p>1 Exhibit 86 Email String Bates 178 2 TORRENT-MDL2875-00156990 to 156993 3 4 Exhibit 87 Email String Bates 179 TORRENT-MDL2875-00030454 to 90463 5 6 Exhibit 88 Valsartan New Process Batch 180 Tracking Bates TORRENT-MDL2875-00090464 7 8 Exhibit 89 Email String Bates 189 TORRENT-MDL2875-00005067 to 5068 9 10 Exhibit 90 FDA News Release 248 11 12 Exhibit 91 Email String Bates 255 TORRENT-MDL2875-00504801 13 14 Exhibit 92 Notification Bates 287 TORRENT-MDL2875-00131255 15 16 Exhibit 93 Email dated 9/7/18 Bates 349 TORRENT-MDL2875-006044834 17 18 Exhibit 94 Torrent Recall Timeline 354 19 EXHIBITS PREVIOUSLY MARKED AND REFERRED TO: 20 Exhibit 1 16 21 Exhibit 2 26 22 Exhibit 3 36 23 Exhibit 4 38 24 Exhibit 5 50 Exhibit 6 51 Exhibit 7 70 Exhibit 8 73</p>	<p>1 DEPOSITION SUPPORT INDEX 2 3 4 Direction to Witness Not to Answer 5 Page Line 6 NONE 7 Request for Production of Documents 8 Page Line 9 NONE 10 Question Marked 11 Page Line 12 NONE 13 14 15 16 17 18 19 20 21 22 23 24</p>
Page 7	Page 9
<p>1 EXHIBITS PREVIOUSLY MARKED AND REFERRED TO 2 Exhibit 9 86 3 Exhibit 10 112 4 Exhibit 12 142 5 Exhibit 13 144 6 Exhibit 14 153 7 Exhibit 15 158 8 Exhibit 16 160 9 Exhibit 19 199 10 Exhibit 20 212 11 Exhibit 21 212 12 Exhibit 22 381 13 Exhibit 23 236 14 Exhibit 25 314 15 Exhibit 26 329 16 Exhibit 27 347 17 Exhibit 28 417 18 Exhibit 29 423 19 20 21 22 23 24</p>	<p>1 2 3 THE VIDEOGRAPHER: We 4 are now on the record. My name is 5 Chris Ritona. I'm the videographer 6 with Golkow Litigation Services. 7 Today's date is May 13, 2021, and 8 the time is approximately 9:07 Eastern. 9 This remote video 10 deposition is being held in the 11 matter of the valsartan, losartan 12 and irbesartan products liability 13 litigation, MDL No. 2875 in the 14 United States District Court, 15 District of New Jersey, civil case 16 number 19-2875. The deponent today 17 is Dawn Chitty. 18 All parties to this 19 deposition are appearing remotely 20 and have agreed to the witness 21 being sworn in remotely. Due to 22 the nature of remote reporting, 23 please pause briefly before 24 speaking to ensure all parties are</p>

<p style="text-align: right;">Page 10</p> <p>1 heard completely.</p> <p>2 All counsel will be</p> <p>3 noted upon the stenographic record.</p> <p>4 The court reporter today is Robin</p> <p>5 Clark and she will now please swear</p> <p>6 in the witness.</p> <p>7 THE STENOGRAPHER: Do</p> <p>8 you want to raise your right hand,</p> <p>9 please? Do you swear the testimony</p> <p>10 you are about to give in this</p> <p>11 deposition will be the truth, the</p> <p>12 whole truth, and nothing but the</p> <p>13 truth, so help you God?</p> <p>14 THE WITNESS: I do.</p> <p>15 -----</p> <p>16 DAWN CHITTY, having been duly</p> <p>17 sworn, was examined and testified as</p> <p>18 follows:</p> <p>19 -----</p> <p>20 BY MS. PENDLEY:</p> <p>21 Q. Good morning. You can go ahead</p> <p>22 and state your name for the record, please.</p> <p>23 A. Dawn Chitty.</p> <p>24 Q. Ms. Chitty, you have been</p>	<p style="text-align: right;">Page 12</p> <p>1 can still answer the question. Okay?</p> <p>2 A. Yes.</p> <p>3 Q. All right. So did you meet</p> <p>4 with your attorneys to prepare for this</p> <p>5 deposition today?</p> <p>6 A. Yes.</p> <p>7 Q. About how long?</p> <p>8 A. Probably four or five hours.</p> <p>9 Q. And you are a former Torrent</p> <p>10 employee, right, you don't currently work</p> <p>11 there?</p> <p>12 A. That's correct.</p> <p>13 Q. And you worked there from</p> <p>14 roughly 2004 to about 2018; is that</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. Is it fair to say that you held</p> <p>18 various regulatory affairs positions while</p> <p>19 you were there?</p> <p>20 A. Yes.</p> <p>21 Q. We'll get into those job titles</p> <p>22 in a little bit more detail later on in the</p> <p>23 depo, but we can agree that patient safety</p> <p>24 is Torrent's number one priority, right?</p>
<p style="text-align: right;">Page 11</p> <p>1 deposited before, correct?</p> <p>2 A. Yes.</p> <p>3 Q. About how many times would you</p> <p>4 say?</p> <p>5 A. Five or six.</p> <p>6 Q. Okay. So you probably know</p> <p>7 most of the basics, but I'm going to remind</p> <p>8 you of a couple of things to make sure</p> <p>9 we're on the same page. So as you heard,</p> <p>10 it's really important we don't speak over</p> <p>11 each other, so just let me get through my</p> <p>12 question before you respond. Okay?</p> <p>13 A. Yes.</p> <p>14 Q. And we're going to need all</p> <p>15 verbal responses from you, because the</p> <p>16 transcript is being taken so no "uh-uhs,"</p> <p>17 "uh-huhs," nodding or shaking your head,</p> <p>18 just anything verbal she can put down on</p> <p>19 the record. Okay?</p> <p>20 A. Yes.</p> <p>21 Q. Your attorney is going to be</p> <p>22 objecting from time to time, I'm pretty</p> <p>23 sure, so when she does, again, unless she</p> <p>24 explicitly instructs you not to answer, you</p>	<p style="text-align: right;">Page 13</p> <p>1 A. Yes.</p> <p>2 Q. We can agree that patient</p> <p>3 safety was your main focus while you worked</p> <p>4 at Torrent?</p> <p>5 A. Safety as well as compliance,</p> <p>6 yes.</p> <p>7 Q. And part of your job at Torrent</p> <p>8 was to make sure that Torrent followed the</p> <p>9 rules and regulations that applied to it,</p> <p>10 right?</p> <p>11 A. As a regulatory advisor within</p> <p>12 the company, I was one of the people who</p> <p>13 advised local U.S. requirements to our</p> <p>14 team, yes, to contribute to making sure we</p> <p>15 meet all requirements.</p> <p>16 Q. Okay. And you understand that</p> <p>17 those requirements or those rules, those</p> <p>18 are in place to protect patients, right?</p> <p>19 A. Correct.</p> <p>20 Q. Those are in place to make sure</p> <p>21 that Torrent sells drugs that are safe,</p> <p>22 right?</p> <p>23 A. Correct.</p> <p>24 Q. And in your role, there's</p>

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1 nothing more important than patient safety;
2 is that fair?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: Patient
6 safety is definitely one of the top
7 priorities, but probably not the
8 only.
9 BY MS. PENDLEY:
10 Q. Okay. Do you agree that
11 pharmaceutical companies like Torrent
12 should be honest with their patients?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: Yes.
16 BY MS. PENDLEY:
17 Q. And we can agree that
18 pharmaceutical companies should give their
19 patients enough information to make a
20 well-informed decision about whether or not
21 to put a drug in their body, right?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: It's

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1 information for the patients, but
2 also information for physicians and
3 people who are, I guess, more of a
4 learned intermediary who can also
5 advise on a situation, because your
6 average person isn't necessarily
7 always capable of understanding all
8 of the technical aspects of a
9 pharmaceutical product.
10 BY MS. PENDLEY:
11 Q. Okay. That's fair. But you
12 would want to provide patients with all the
13 information they need to make that
14 decision?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: We provide
18 doctors and patients with accurate
19 information. Who makes that
20 decision is not something I'm aware
21 of, so.
22 BY MS. PENDLEY:
23 Q. And your job requires you to
24 regularly communicate with the FDA?

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1 A. Yes.
2 Q. And when you communicated with
3 the FDA, you understood it was important to
4 be honest with them too, right?
5 A. Yes.
6 Q. And we can agree that you
7 should provide the FDA with all the
8 information they need to fully assess the
9 situation?
10 MS. NAGLE: Objection to
11 form.
12 THE WITNESS: Yes.
13 BY MS. PENDLEY:
14 Q. And you did that when you
15 worked at Torrent, right?
16 A. Correct.
17 Q. Let's pull up LP 1110. This
18 has previously marked as Torrent Exhibit 1.
19 Ms. Chitty, do you recognize this?
20 A. That looks like the Torrent web
21 page.
22 Q. Great. This is from Torrent's
23 website. It's publicly accessible if you
24 just go to the internet and pull this up,

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1 so you look under the word "manufacturing"
2 in here. And the first sentence it says
3 "At Torrent, we strongly believe in
4 providing quality medicines at affordable
5 price to the patients." Explain quality
6 for me, what does Torrent mean when they
7 use the word "quality"?
8 MS. NAGLE: Objection.
9 Form and foundation.
10 THE WITNESS: Quality in
11 a general sense means that it meets
12 the standards that have been set by
13 the regulatory bodies that we
14 interact with and are governed by.
15 BY MS. PENDLEY:
16 Q. Does it mean safe?
17 MS. NAGLE: Objection.
18 Form and foundation.
19 THE WITNESS: That's
20 kind of really beyond my expertise
21 to decide if quality also means
22 safe.
23 BY MS. PENDLEY:
24 Q. Okay. And we mentioned that

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1 this is their public website, so if a
2 customer were to go to Torrent's website
3 and they would see this sentence, do you
4 understand that customers think they're
5 buying a quality safe drug from Torrent?
6 MS. NAGLE: Objection.
7 Form and foundation.
8 THE WITNESS: I really
9 can't speak to the way an
10 individual reader would interpret
11 the word "quality."
12 BY MS. PENDLEY:
13 Q. Do you agree that customers
14 should be getting a safe drug?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: Safe is,
18 again, somewhat of a vague term.
19 The products that Torrent
20 manufactures meet requirements and
21 quality standards, as I had said
22 before.
23 BY MS. PENDLEY:
24 Q. All right. How do you define

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1 safe?
2 A. It's really not within my
3 expertise to define safe.
4 Q. All right. Let's put expertise
5 to the side for a second. If you were
6 asked as a layperson, what does safe mean,
7 what's your response?
8 A. Safe means that the product
9 you're taking helps more than it hurts your
10 personal situation. There's always a
11 benefit and a risk associated with
12 everything that you take.
13 Q. Okay. So helps more than it
14 hurts. Do you agree that patients should
15 be getting a medication that helps more
16 than it hurts?
17 A. Yes.
18 Q. Then we agree in order to have
19 a quality finished product, you would have
20 to have quality ingredients, right?
21 MS. NAGLE: Objection,
22 form.
23 THE WITNESS: Yes.
24

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1 BY MS. PENDLEY:
2 Q. If you have an issue with an
3 ingredient that goes into a drug, you could
4 have an issue with the final product; is
5 that fair?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: It's a
9 fairly accurate statement, yes.
10 BY MS. PENDLEY:
11 Q. For valsartan that was sold in
12 the U.S., Torrent is what is called a
13 finished dose manufacturer, right?
14 A. Yes.
15 Q. Okay. So finished dose means
16 the drug is done being produced once it
17 leaves Torrent's facility, right?
18 A. Finished dose means Torrent is
19 making the product that patients and
20 consumers will eventually consume and use.
21 Q. Okay. Is it ready to be
22 consumed when it leaves Torrent's facility?
23 A. Yes.
24 Q. And Torrent is essentially the

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1 last line of defense for that drug before
2 it goes to customers, right?
3 MS. NAGLE: Objection.
4 Form and foundation.
5 THE WITNESS: I would
6 not characterize it as the last
7 line of defense, but we do the last
8 checks to make sure that it meets
9 current regulatory standards before
10 it is released to the public.
11 BY MS. PENDLEY:
12 Q. And to make sure it meets
13 current regulatory standards, that includes
14 things like testing the drug, right?
15 MS. NAGLE: Objection.
16 Form, foundation.
17 THE WITNESS: Products
18 are tested before they leave the
19 product -- I'm sorry, before they
20 leave the plant, yes, but it's kind
21 of not my area. I wasn't involved
22 in those types of release
23 activities.
24

<p style="text-align: right;">Page 22</p> <p>1 BY MS. PENDLEY:</p> <p>2 Q. Okay. And because patient</p> <p>3 safety is very important at Torrent, like</p> <p>4 you told me earlier, Torrent had a</p> <p>5 responsibility to ensure that its drugs are</p> <p>6 safe when they leave its facility, right?</p> <p>7 MS. NAGLE: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Again,</p> <p>10 safe is a non -- I would say,</p> <p>11 regulatory word. They are required</p> <p>12 to make sure it meets current</p> <p>13 specifications and is compliant</p> <p>14 with the agreed-upon standards</p> <p>15 before it leaves the plant.</p> <p>16 BY MS. PENDLEY:</p> <p>17 Q. Okay. You know we're here</p> <p>18 today because the medication valsartan was</p> <p>19 recalled, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And it was recalled because it</p> <p>22 contained nitrosamines, right?</p> <p>23 A. Correct.</p> <p>24 Q. Specifically NDMA and NDEA,</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. All right. We're going to look</p> <p>2 at this first row where it says valsartan</p> <p>3 to the left and we're going to look at</p> <p>4 those levels. Do you see where it's the</p> <p>5 third column from the left, acceptable</p> <p>6 intake for NDMA nanograms per day. Do you</p> <p>7 see where it says 96?</p> <p>8 A. Yes.</p> <p>9 Q. And you see the next column</p> <p>10 over says .3 parts per million, right?</p> <p>11 A. Yes.</p> <p>12 Q. And for NDEA, you see that it's</p> <p>13 26.5 nanograms per day and .083 parts per</p> <p>14 million?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. So you understand this</p> <p>17 is, like, the daily acceptable threshold</p> <p>18 limit set by the FDA, right?</p> <p>19 A. Yes.</p> <p>20 Q. The medications cannot,</p> <p>21 specifically, valsartan cannot contain more</p> <p>22 than those levels of NDMA and NDEA, right?</p> <p>23 A. Was that a question? Yes.</p> <p>24 Q. Yes. So the FDA created these</p>
<p style="text-align: right;">Page 23</p> <p>1 right?</p> <p>2 A. Is that a question? Yeah, to</p> <p>3 my knowledge, those were the two</p> <p>4 impurities.</p> <p>5 Q. Okay. Let's pull up the FDA</p> <p>6 limits website, it's at LP 1469.</p> <p>7 EXHIBIT TECH: I'm</p> <p>8 sorry, what's the LP number?</p> <p>9 MS. PENDLEY: 1469.</p> <p>10 EXHIBIT TECH: One</p> <p>11 second.</p> <p>12 - - - - -</p> <p>13 (Interim Limits for NDMA, NDEA,</p> <p>14 and NMBA in Angiotensin II Receptor</p> <p>15 Blockers (ARBs) marked Torrent Exhibit</p> <p>16 77 for identification.)</p> <p>17 - - - - -</p> <p>18 BY MS. PENDLEY:</p> <p>19 Q. What has been marked as Torrent</p> <p>20 Exhibit 77, Ms. Chitty, this is a portion</p> <p>21 of the page from the FDA websites that sets</p> <p>22 out the limits for nitrosamines. Do you</p> <p>23 see this?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 25</p> <p>1 limits in order to keep customers safe, we</p> <p>2 can agree?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And it's up to the</p> <p>5 manufacturers to ensure that their products</p> <p>6 don't contain more nitrosamines than this,</p> <p>7 right?</p> <p>8 MS. NAGLE: Objection,</p> <p>9 foundation.</p> <p>10 THE WITNESS: Yes, but I</p> <p>11 think the timing of this</p> <p>12 information is somewhat -- somewhat</p> <p>13 critical. That web page is dated</p> <p>14 from 2021, not at the time we were</p> <p>15 initially making decisions related</p> <p>16 to the recall.</p> <p>17 BY MS. PENDLEY:</p> <p>18 Q. Move to strike as</p> <p>19 nonresponsive. You know that it helped the</p> <p>20 manufacturers to ensure that their drugs</p> <p>21 don't contain more nitrosamines than this,</p> <p>22 right, based on what we know today?</p> <p>23 MS. NAGLE: Objection,</p> <p>24 foundation.</p>

<p>Page 26</p> <p>1 THE WITNESS: Based upon</p> <p>2 once these standards were</p> <p>3 established, yes.</p> <p>4 BY MS. PENDLEY:</p> <p>5 Q. Pull up LP 1102. It was</p> <p>6 previously marked as Torrent Exhibit 2.</p> <p>7 Now, just looking at the cover page here,</p> <p>8 have you seen this before?</p> <p>9 A. Not that I recall.</p> <p>10 Q. So looking in the middle of the</p> <p>11 page, we see that it is called</p> <p>12 N-nitrosodimethylamine, that means NDMA,</p> <p>13 right?</p> <p>14 A. I'm not sure; I believe that's</p> <p>15 what that stands for.</p> <p>16 Q. We see that it's published,</p> <p>17 looking down at the bottom of the page, in</p> <p>18 2002, right?</p> <p>19 A. That is the date. I'm not sure</p> <p>20 if that's a publication date or not.</p> <p>21 Q. And it's published by the World</p> <p>22 Health Organization, right?</p> <p>23 A. It appears so, yes.</p> <p>24 Q. I'll show you what is marked as</p>	<p>Page 27</p> <p>1 page 4. Looking at the right-hand side,</p> <p>2 third paragraph down, you can blow that up.</p> <p>3 It says "Based upon laboratory studies in</p> <p>4 which tumours have been introduced in all</p> <p>5 species examined at relatively low doses,</p> <p>6 NDMA is clearly carcinogenic." Do you see</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. What does carcinogenic mean?</p> <p>10 MS. NAGLE: Objection,</p> <p>11 foundation.</p> <p>12 THE WITNESS: I'm really</p> <p>13 not a toxicologist. To my basic</p> <p>14 knowledge, it means that it</p> <p>15 potentially causes cancer.</p> <p>16 BY MS. PENDLEY:</p> <p>17 Q. Let's look at the last sentence</p> <p>18 on that paragraph, "Qualitatively, the</p> <p>19 metabolism of NDMA appears to be similar in</p> <p>20 humans and animals; as a result, it is</p> <p>21 considered highly likely that NDMA is</p> <p>22 carcinogenic to humans, potentially at</p> <p>23 relatively low levels of exposure." That</p> <p>24 means it can give people cancer, right?</p>	<p>Page 28</p> <p>1 MS. NAGLE: Objection.</p> <p>2 Form and foundation.</p> <p>3 THE WITNESS: I'm really</p> <p>4 not, again, a toxicologist and</p> <p>5 qualified to interpret fully what</p> <p>6 that sentence means.</p> <p>7 BY MS. PENDLEY:</p> <p>8 Q. You just told me carcinogenic</p> <p>9 means causes cancer, right?</p> <p>10 MS. NAGLE: Objection,</p> <p>11 form.</p> <p>12 THE WITNESS: I don't</p> <p>13 believe that's exactly what I said</p> <p>14 and I said it potentially causes</p> <p>15 cancer.</p> <p>16 BY MS. PENDLEY:</p> <p>17 Q. Okay. So potentially causes</p> <p>18 cancer to humans is what that says?</p> <p>19 A. Again, it's outside of my area</p> <p>20 of expertise. I am really not qualified or</p> <p>21 knowledgeable to draw any conclusions from</p> <p>22 that text.</p> <p>23 Q. And you know what the English</p> <p>24 word "carcinogenic" means, right?</p>	<p>Page 29</p> <p>1 A. Generally.</p> <p>2 Q. Okay. So the sentence NDMA is</p> <p>3 carcinogenic to humans tells us that NDMA</p> <p>4 likely causes cancer to humans, right?</p> <p>5 A. It says "highly likely," and</p> <p>6 again, I'm not really qualified to draw any</p> <p>7 conclusions beyond what that says.</p> <p>8 Q. Okay. Well, it goes on to say</p> <p>9 it could be -- "NDMA is carcinogenic to</p> <p>10 humans potentially at relatively low levels</p> <p>11 of exposure." That last part means it</p> <p>12 doesn't require very much NDMA at all to be</p> <p>13 carcinogenic, right?</p> <p>14 MS. NAGLE: Objection.</p> <p>15 Form and foundation.</p> <p>16 THE WITNESS: It says</p> <p>17 potentially, so I don't really know</p> <p>18 how to interpret that.</p> <p>19 BY MS. PENDLEY:</p> <p>20 Q. You know how to interpret low</p> <p>21 levels of exposure, right?</p> <p>22 MS. NAGLE: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: Low levels</p>
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1 can mean a variety of things.
2 BY MS. PENDLEY:
3 Q. Okay. We'll come back to this
4 and I'll show you what I'm talking about in
5 a minute. Let's go to page 5. Left-hand
6 side, first paragraph. The last sentence
7 says "NDMA is a genotoxic carcinogenic, and
8 exposure to be reduced to the extent
9 possible." Do you see that?
10 A. Yes.
11 Q. So exposure should be reduced
12 to the extent possible, that means try to
13 expose people to it as little as possible,
14 right?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: It means
18 what it says, reduce to the extent
19 possible.
20 BY MS. PENDLEY:
21 Q. Okay. It means try to keep
22 people away from it?
23 MS. NAGLE: Objection,
24 form.

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1 MS. PENDLEY: Right?
2 THE WITNESS: I wouldn't
3 necessarily agree with the way you
4 stated it. I can't really
5 elaborate beyond what's written
6 here again.
7 BY MS. PENDLEY:
8 Q. What does reduced mean?
9 A. To decrease.
10 Q. Okay. So exposure should be
11 decreased to the extent possible, do you
12 agree with that?
13 MS. NAGLE: Objection.
14 Form and foundation.
15 THE WITNESS: It pretty
16 much says the same thing as to what
17 is written on the page and I can't
18 elaborate beyond that as to intent.
19 BY MS. PENDLEY:
20 Q. Right. We saw at the beginning
21 of this document was published in 2002,
22 which is well before the recall that
23 happened in 2018, right?
24 A. 2002 is before 2018, yes.

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1 Q. So when Torrent was told that
2 NDMA is what was in their drug, people at
3 your company understood how dangerous NDMA
4 was, right?
5 MS. NAGLE: Objection to
6 form and foundation.
7 THE WITNESS: I can't
8 really speak to what other people
9 were aware of.
10 BY MS. PENDLEY:
11 Q. Were you aware of how dangerous
12 NDMA is?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: No, not
16 until we started receiving some
17 information from FDA.
18 BY MS. PENDLEY:
19 Q. When you first got the notice
20 that NDMA was in a drug you were assisting
21 with, you did not know that it was a
22 carcinogen?
23 A. That is a compound or a
24 by-product that I was not familiar with

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1 prior to conversations around the sartan
2 products started in 2018.
3 Q. This document uses the word
4 "genotoxic." What does that mean?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: Yeah, I'm
8 not sure.
9 BY MS. PENDLEY:
10 Q. You don't know what the word
11 "genotoxic" means?
12 A. Not specifically, no.
13 Q. Do you know that it means
14 causes damage to DNA?
15 A. If that's your definition,
16 again, I couldn't give you a concise
17 definition myself.
18 Q. Do you know that things that
19 are genotoxic cause mutations?
20 MS. NAGLE: Objection to
21 form.
22 THE WITNESS: No, that's
23 not, again, my area of expertise.
24 I'm not a toxicologist, so I don't

<p style="text-align: right;">Page 34</p> <p>1 have a background in this type of</p> <p>2 area.</p> <p>3 BY MS. PENDLEY:</p> <p>4 Q. Okay. But you've worked in the</p> <p>5 pharmaceutical industry for, like, 20</p> <p>6 years, right?</p> <p>7 A. Yes.</p> <p>8 Q. And you don't know what the</p> <p>9 word "genotoxic" means?</p> <p>10 A. We have experts that advise on</p> <p>11 these types of issues. So again, if</p> <p>12 someone asked me for a specific definition</p> <p>13 of genotoxic, I would go to my</p> <p>14 toxicologist. I wouldn't make it up</p> <p>15 myself.</p> <p>16 Q. Okay. Well, your toxicologist</p> <p>17 isn't here, so I'm asking you, what do you</p> <p>18 think the word "genotoxic" means?</p> <p>19 MS. NAGLE: Objection.</p> <p>20 Form and foundation.</p> <p>21 THE WITNESS: Again, I,</p> <p>22 you know, I only have vague ideas</p> <p>23 of what this means.</p> <p>24</p>	<p style="text-align: right;">Page 36</p> <p>1 MS. NAGLE: Objection.</p> <p>2 Form and foundation.</p> <p>3 THE WITNESS: There are</p> <p>4 limits on all drugs specifically</p> <p>5 and there are some allowable limits</p> <p>6 for things that are potentially</p> <p>7 perceived as genotoxic or</p> <p>8 carcinogenic, so it's not an all or</p> <p>9 nothing. There are some</p> <p>10 international standards that are</p> <p>11 set around these types of</p> <p>12 impurities.</p> <p>13 BY MS. PENDLEY:</p> <p>14 Q. Okay. Let me reask that. You</p> <p>15 wouldn't want more than the FDA threshold</p> <p>16 of genotoxic impurity in your drug?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Let's pull up LP 1064.</p> <p>19 This was previously marked as Torrent</p> <p>20 Exhibit 3. So this is an email and we're</p> <p>21 going to look at the attachment of the</p> <p>22 email. So if we can kind of zoom in on</p> <p>23 this top section so we can see who the</p> <p>24 email was sent to. We see that it was sent</p>
<p style="text-align: right;">Page 35</p> <p>1 BY MS. PENDLEY:</p> <p>2 Q. Give me one of those vague</p> <p>3 ideas.</p> <p>4 A. It's a word that has a negative</p> <p>5 connotation. It does say the word "toxic"</p> <p>6 as part of it. So it is something that is</p> <p>7 potentially, potentially harmful.</p> <p>8 Q. Okay. Can we agree that</p> <p>9 genotoxic compounds or whatever they may be</p> <p>10 should be taken very seriously; is that</p> <p>11 fair?</p> <p>12 MS. NAGLE: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MS. PENDLEY:</p> <p>16 Q. Obviously, the company should</p> <p>17 take necessary steps to identify genotoxic</p> <p>18 impurities, right?</p> <p>19 MS. NAGLE: Objection.</p> <p>20 Form and foundation.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MS. PENDLEY:</p> <p>23 Q. You don't want genotoxic</p> <p>24 impurities in your drug; is that fair?</p>	<p style="text-align: right;">Page 37</p> <p>1 on August 18, 2018. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And we see it's sent from</p> <p>4 Sanjay Sharma. Who is that?</p> <p>5 A. I don't recall. It's been a</p> <p>6 number of years since I left and so I have</p> <p>7 been having a hard time remembering exactly</p> <p>8 who some of the folks are that were</p> <p>9 participating in these activities. So I</p> <p>10 don't remember who Sanjay is.</p> <p>11 Q. Okay. We see that it was sent</p> <p>12 to you, right?</p> <p>13 A. Yes.</p> <p>14 Q. And so you worked for Torrent</p> <p>15 U.S., right?</p> <p>16 A. Yes.</p> <p>17 Q. There's also a Torrent --</p> <p>18 that's not the official name, but Torrent</p> <p>19 India as well, right?</p> <p>20 A. Yes.</p> <p>21 Q. Does Sanjay work for Torrent</p> <p>22 U.S. or Torrent India?</p> <p>23 A. By his email, he looks like he</p> <p>24 works for Torrent in India, because it has</p>

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1 a dot com extension on it.
2 Q. Okay, it's a torrentpharma.com
3 is India and U.S. is torrentpharma.us?
4 A. I believe so, yeah.
5 Q. Okay. We can see the
6 attachment here is HHE valsartan,
7 amlodipine, HCTZ medical assessment.
8 That's what we're going to look at. So if
9 we could pull up LP 1065. This was
10 previously marked as Torrent Exhibit 4. We
11 can see that this is a Torrent document,
12 right, by that logo up in the right-hand
13 corner?
14 A. Yes.
15 Q. Do you remember seeing this
16 document?
17 A. I don't recall specifically,
18 but it was obviously sent to me.
19 Q. We can see that it's called
20 "Health Hazard Evaluation
21 Amlodipine/Valsartan/Hydrochlorothiazide."
22 Did Torrent India draft this document as
23 far as you're aware?
24 A. As far as I'm aware, yes.

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1 Q. Look at page 3. And under that
2 heading "Effect in Animals," go to that
3 first paragraph, this says "NDMA has been
4 found to increase the occurrence of cancer
5 in animal studies. Based on these animal
6 studies, NDMA is considered as a probable
7 human carcinogen, a chemical that can
8 increase the risk of cancer in humans." Do
9 you see that?
10 A. Yes.
11 Q. We just saw the World Health
12 Organization document that said it's highly
13 likely NDMA is a carcinogen. Do you
14 remember that?
15 A. Yes.
16 Q. And here Torrent chose the
17 phrase "probable human carcinogen." You do
18 understand that NDMA is a probable human
19 carcinogen, because at this point, it's
20 unethical to expose people to NDMA to
21 determine its true carcinogenic effect,
22 right?
23 MS. NAGLE: Form and
24 foundation.

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1 THE WITNESS: Can you
2 repeat the question? I'm sorry,
3 that was a bit long.
4 BY MS. PENDLEY:
5 Q. Yeah. And I'm emphasizing the
6 word "probable," to be clear, so it is a
7 probable rather than a certain human
8 carcinogen, because at this point, we can't
9 expose people to it, right?
10 MS. NAGLE: Objection.
11 Form and foundation.
12 THE WITNESS: I don't
13 think I understand the question as
14 to how you're tying probable to not
15 exposing people. I'm sorry, I'm
16 just not understanding the
17 question.
18 BY MS. PENDLEY:
19 Q. It was only a probable human
20 carcinogen, probable meaning not certain,
21 right?
22 A. If that's your definition of
23 probable, sure. I'm not sure if there are
24 other definitions or medical implications

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1 of the word "probable." I'm not sure.
2 Q. What is your definition of the
3 word "probable"?
4 A. It may be.
5 Q. Okay. So it may be a human
6 carcinogen, right, as opposed to it
7 definitely is a human carcinogen, because
8 we're not allowed to give NDMA to people.
9 Do you understand that?
10 MS. NAGLE: Objection to
11 form and foundation.
12 THE WITNESS: Again, I'm
13 not understanding where your
14 conclusion of we can't give it to
15 people is coming from.
16 BY MS. PENDLEY:
17 Q. Okay. We do know this document
18 tells that NDMA is so harmful to animals
19 that we can't intentionally give it to
20 people, right?
21 MS. NAGLE: Objection to
22 form.
23 THE WITNESS: That is
24 not, I believe, what that sentence

<p style="text-align: right;">Page 42</p> <p>1 is saying by my interpretation. 2 BY MS. PENDLEY: 3 Q. We followed the World Health 4 Organization said NDMA is high likely to be 5 a carcinogen. 6 I want to take you to the next 7 page and we're going to look at the levels 8 of NDMA in Torrent's valsartan. Okay? If 9 you could zoom in on Table 2. See where it 10 says Table 2 and the colon, it says 11 amlodipine/valsartan/hydrochlorothiazide? 12 A. Yes. 13 Q. And then these columns and in 14 this chart, you can see the fifth column of 15 the left says ppm level tested at Huahai. 16 Do you see that? 17 A. Yes. 18 Q. Ppm means parts per million, 19 right? 20 A. Yes. 21 Q. And Huahai, that the API 22 manufacturer? 23 A. Correct. 24 Q. You see number one, it lists</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MS. PENDLEY: 2 Q. It's more than triple that, 3 right? 4 A. Yes. 5 Q. More than 100 times the limit, 6 right? 7 A. Yes. 8 Q. Pull up a calculator real 9 quick, if we can, Chris. 63.4 divided by 10 .3, so we can see that 63.4 parts per 11 million is 211 times higher than the FDA 12 threshold for NDMA, right? 13 A. These based on a purely 14 numerical standpoint, yes, but I think 15 you're comparing apples and oranges, 16 because my understanding of this ppm level 17 here is the level in the API. The previous 18 limit you're referencing was the daily 19 limit in consuming the maximum dose of drug 20 product. So it's really not an 21 apples-to-apples comparison. 22 Q. The maximum dose of valsartan 23 is 320 milligrams, right? 24 A. I don't recall.</p>
<p style="text-align: right;">Page 43</p> <p>1 amlodipine, valsartan, HCTZ and the batch 2 number. Do you see that? 3 A. Yes. 4 Q. And all the way down the 5 spreadsheet, it's different batch numbers, 6 right, 14 different ones? 7 A. Yes, there appears to be 14 8 there. 9 Q. Looking at that first row, 10 under the ppm level, Huahai received 63.4. 11 Do you see that? 12 A. Yes. 13 Q. So earlier when we looked at 14 the FDA levels, it says no more than .3 15 parts per million of NDMA valsartan, right? 16 A. I don't recall specifically, 17 but if that's what the document says, then 18 that's fine. 19 Q. 63.4 is significantly more than 20 .3, right? 21 MS. NAGLE: Objection to 22 form. 23 THE WITNESS: 63.4 is 24 higher than .3.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Okay. You see that, if we 2 could take the calculator down real quick, 3 under product name, it says amlo/val/HCTZ 4 and you can see the milligrams listed for 5 valsartan is 320, right? 6 A. That details that there are 7 320 milligrams of valsartan in that tablet. 8 That does not necessarily equate to the 9 maximum dose. 10 Q. Okay. 11 A. Again, apples and oranges. 12 Q. Let's take this down real 13 quick. I want to pull up LP 1469 again. 14 You can see right there next to valsartan, 15 it says maximum daily dose milligrams per 16 day, 320, right? 17 A. Okay, yes. 18 Q. Okay. And it says for 320, the 19 acceptable intake for NDMA parts per 20 million is .3? 21 A. That is what the table says. 22 Q. Okay. If we do .3 parts per 23 million times 320, that puts it at 24 96 nanograms per day, right?</p>

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1 A. Yes.

2 Q. Now that we have got that,

3 let's go back LP 1065, once again, we've

4 got that ppm level tested at Huahai is 211

5 times more NDMA than the maximum daily

6 exposure limit, right?

7 A. That is the level in the API

8 before it is processed into the final drug

9 product. That's the way I understand the

10 information in this table. That is not the

11 limit of NDMA in the finished dose product.

12 Q. Okay. 63.4 parts per million

13 in NDMA in batch one. I want you to look

14 at the rest of these batches with me.

15 Batch two, same thing, 63.4, and we can see

16 all the way down, unless it says not

17 available, they're all upwards of 60,

18 right?

19 A. Yes, for the ones where there

20 is a given number given.

21 Q. So they're all over 200 times

22 over the amount of NDMA that the FDA says

23 people can be exposed to?

24 A. Roughly. And again, those are

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1 quantities in the API batch before it's

2 unprocessed into finished drug product.

3 Q. So this document shows us that

4 the contamination was in valsartan that you

5 guys knew about at this point was

6 significantly higher than the FDA limit; is

7 that fair?

8 MS. NAGLE: Objection to

9 form.

10 THE WITNESS: No, I

11 don't agree with that conclusion,

12 because, again, the way I interpret

13 this table, this is the amount of

14 NDMA in the API before it is

15 processed into drug product. When

16 you manufacture drug products,

17 there are opportunities to continue

18 to remove impurities sometimes. So

19 I don't interpret this as

20 necessarily meaning that the ppm

21 level for this batch of product, if

22 you were to test a tablet, is 63.4.

23 BY MS. PENDLEY:

24 Q. Why is that your interpretation

Page 48

1 of this document?

2 A. Because the vendor of the API

3 would not have been testing our tablets.

4 They sell API, they test API, they had, to

5 my knowledge, no reason to be testing our

6 tablets.

7 Q. So the HP or Huahai would never

8 be testing Torrent finished dose product?

9 A. I can't say never, but that's

10 not a standard practice and I'm not aware

11 that it necessarily happened with these

12 products.

13 Q. Well, was Torrent testing the

14 API that it received from Hauhai?

15 A. Torrent has procedures on what

16 they test whenever we receive a specific

17 component that we used in making drugs,

18 yes.

19 Q. Did Torrent confirm Hauhai's

20 testing for these batches?

21 A. I don't really know. That

22 document doesn't detail that here.

23 Q. We can agree that the issue

24 with valsartan is it was the API that was

Page 49

1 contaminated, right, valsartan API?

2 A. To my knowledge, the valsartan

3 API contained the impurity, yes.

4 Q. Okay. This pill has

5 320 milligrams of valsartan API in it,

6 correct? Line 1, we're looking at.

7 A. The first line that as

8 320 milligrams, yes, of valsartan.

9 Q. And it is the API that is

10 contaminated, right?

11 A. The API contains this impurity,

12 yes.

13 Q. Do you believe that the

14 contamination or impurities are somehow

15 removed when processed into finished

16 product?

17 A. They potentially can be.

18 Q. There's no evidence that NDMA

19 contamination is removed when processed

20 into finished product, right?

21 MS. NAGLE: Objection to

22 form.

23 THE WITNESS: Just

24 speaking from my general knowledge,

Page 50

1 there is an ability to sometimes
2 decrease impurity levels through
3 processing and manufacturing of
4 drug products.
5 BY MS. PENDLEY:
6 Q. Do you know that to be true
7 specifically for NDMA?
8 A. Specifically for NDMA, no.
9 Q. Do you know it to be true
10 specifically for NDEA?
11 A. No.
12 Q. Let's look at LP 1034,
13 previously marked as Torrent Exhibit 5.
14 Same idea, this is the email and then we're
15 going to look at the attachment. So once
16 Torrent found out that its valsartan
17 product was contaminated, it put out a
18 press release to customers, right?
19 A. I'm sorry, can you repeat the
20 question?
21 Q. Once Torrent found out its
22 valsartan product was contaminated, it put
23 out a press release to customers?
24 A. I don't remember the sequence

Page 51

1 of events specifically without seeing some
2 documents to detail the timing. The press
3 release was part of our recall activities.
4 Q. And we can see from this email,
5 it's August 18, 2018, right?
6 A. That is the date of the email,
7 yes.
8 Q. And it's sent to you. Do you
9 see that?
10 A. Yes.
11 Q. And then this is another email
12 that's sent from Sanjay Sharma at Torrent
13 India, right?
14 A. Yes.
15 Q. We can see the attachment is
16 valsartan Q&A final document. That's what
17 we are going to look at. If we can pull up
18 LP 1030 tab, previously marked as Torrent
19 6. So I'm going to look at number two,
20 "Why is this product being recalled?"
21 "This product is being recalled
22 due to the detection of trace amounts of an
23 unexpected impurity found in active
24 pharmaceutical ingredient or (API)."

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1 So despite the testing of we
2 just looked at, when Torrent was informing
3 customers of the contamination issue, they
4 chose the word "trace." Do you see that?
5 A. Yes.
6 Q. How do you define trace?
7 A. Trace means small.
8 Q. Like not very much, right?
9 MS. NAGLE: Objection to
10 form.
11 THE WITNESS: As I said,
12 small.
13 BY MS. PENDLEY:
14 Q. And you remember looking at
15 that World Health Organization document, it
16 only takes small amounts of NDMA to be
17 dangerous, right?
18 MS. NAGLE: Objection to
19 form.
20 THE WITNESS: I don't
21 remember what the term was used in
22 the World Health Organization
23 document.
24

Page 53

1 BY MS. PENDLEY:
2 Q. Okay. Do you agree that it
3 said relatively low doses of NDMA can be
4 dangerous?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: I believe
8 it said relatively low doses.
9 BY MS. PENDLEY:
10 Q. All right. We can think about
11 it from a common sense standpoint too,
12 because think about the concept of parts
13 per million, right? So if you have one
14 part per million that is one in a million,
15 right?
16 A. Sure.
17 Q. Okay. And the FDA limit for
18 NDMA is .3 parts per million, so it's even
19 smaller than one part per million?
20 A. .3 is smaller than one, yes.
21 Q. So .3 parts per million is a
22 very small amount of something, we can
23 agree?
24 MS. NAGLE: Objection,

Page 54

1 form.
2 THE WITNESS: Small,
3 trace, they're all relative terms.
4 BY MS. PENDLEY:
5 Q. Well, we can agree that Torrent
6 used the word "trace" in order to minimize
7 the impact of finding a carcinogen in their
8 drug, right?
9 MS. NAGLE: Objection to
10 form and foundation.
11 THE WITNESS: No, I
12 don't agree that was the intention
13 of the word "trace."
14 BY MS. PENDLEY:
15 Q. Okay. Well, we can agree this
16 document does not say Torrent detected over
17 200 times the FDA limit of NDMA, right?
18 A. At the time this was written, I
19 don't recall if there was an acceptable
20 limit in August of 2018 or if it was, I
21 don't recall what it was. Again, that .3
22 is data from 2021 by the document you
23 showed.
24 Q. That document was pulled from

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1 the internet in 2021. It's not really new
2 information, but you did know that the FDA
3 limit certainly wasn't, like, 50 parts per
4 million for NDMA, right?
5 MS. NAGLE: Objection to
6 form.
7 THE WITNESS: I would
8 have to see documents. I have no
9 idea what day FDA put out specific
10 numbers, so it's been almost three
11 years. So if you can show me
12 documents as to what FDA
13 communicated as a limit at this
14 time, then we can discuss that in
15 context.
16 BY MS. PENDLEY:
17 Q. You have no memory of what you
18 guys thought the limit might be back when
19 this was published?
20 MS. NAGLE: Objection to
21 form.
22 THE WITNESS: A memory
23 from three years ago, no.
24

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1 BY MS. PENDLEY:
2 Q. All right. Look now at number
3 three. It's interesting you told me you
4 guys weren't aware of the FDA limit at this
5 point, if you look at that highlighted
6 sentence it says, "The amounts of NDMA in
7 air, water, or food that result in health
8 effects. Consuming up to 96 nanograms per
9 day is considered reasonably safe." Do you
10 see that?
11 A. Actually no, I do not. Hold
12 on.
13 Q. It's the last sentence of the
14 paragraph that's highlighted in bright
15 yellow.
16 A. So the last sentence, I see
17 the -- oh, that. Okay. I see what you
18 were referring to.
19 Q. That 96 nanograms of NDMA per
20 day, did Torrent make that up?
21 A. I'm not sure where that came
22 from. Again, I wasn't responsible for kind
23 of putting together this type of
24 information. It's not my area of

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1 expertise.
2 Q. You reviewed it when they sent
3 it to you, right?
4 A. I did review it, yes.
5 Q. Did you ever think, hmm, how
6 did they come up with 96 nanograms per day?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: I'm
10 confident that our experts within
11 Torrent whose job it is to evaluate
12 this information took it from
13 reasonable, accurate sources. It's
14 not my job to second guess them.
15 BY MS. PENDLEY:
16 Q. You think they maybe got it
17 from the FDA?
18 A. I don't know where they got it.
19 Q. We can agree that 96 nanograms
20 per day, if you do that math we just did,
21 you did .3 parts per million times
22 320 milligrams, you get 96 nanograms of
23 NDMA, right?
24 A. Yes.

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1 Q. That's probably where that
2 number came where, do you agree?
3 MS. NAGLE: Objection to
4 form.
5 THE WITNESS: Again, I
6 don't know where that number in
7 this document specifically came
8 from.
9 BY MS. PENDLEY:
10 Q. Right? It make sense if
11 Torrent was relying on FDA limits at this
12 time as opposed to making up arbitrary
13 numbers, right?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: As I
17 stated, I don't recall where this
18 number came from specifically.
19 BY MS. PENDLEY:
20 Q. Okay. We can see in 2018, you
21 guys at least thought that NDMA threshold
22 was 96 nanograms per day based on this
23 document?
24 A. Could you repeat that question?

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1 Sorry, you cut out just a little bit.
2 Q. From this document, we can see
3 that in August 2018, Torrent thought
4 consuming up to 96 nanograms of NDMA per
5 day was the limit, right?
6 MS. NAGLE: Objection to
7 form.
8 THE WITNESS: It stated
9 that it's considered reasonably
10 safe for ingestion.
11 BY MS. PENDLEY:
12 Q. How?
13 A. I don't know if I interpret
14 that as a strict limit, but.
15 Q. Go to LP 1137. Let's do 1337,
16 sorry. This has been marked as Torrent
17 Exhibit 78. You can see across the top it
18 says "Valsartan API NDMA and NDEA Results."
19 Do you see that?
20 A. Yes.
21 -----
22 (Valsartan API NDMA and NDEA
23 Results marked Torrent Exhibit 78 for
24 identification.)

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1 -----
2 BY MS. PENDLEY:
3 Q. And if we look at the chart, we
4 see that last column is NDEA content in
5 parts per million. So I want to look at
6 this first row where it says 14.13. Do you
7 remember from that other document, the ppm
8 limit for NDEA is .083, right?
9 A. I don't recall that, but if
10 that's what it says, that's fine.
11 Q. Okay. 14.13 is significantly
12 higher than .083, right?
13 MS. NAGLE: Objection to
14 form.
15 THE WITNESS: It is
16 higher.
17 BY MS. PENDLEY:
18 Q. If we can pull up the
19 calculator again, please. If we could do
20 14.13 divided by .083. We can see that the
21 NDEA content in this batch is 170 times
22 higher than the threshold limit, right?
23 A. I agree with the math.
24 Q. Okay. Let's go down and look

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1 at rows 14 and 15. 15.29, that's also
2 higher than .083, right?
3 A. Yes.
4 Q. Pull up the calculator. We're
5 going to do 15.29 divided by .083. 184
6 times higher than the limit. Do you see
7 that?
8 A. Yes.
9 Q. Let's go to batches 19, we'll
10 go to that one first. 13.93, same thing,
11 let's do 13.93 divided by .083. 167 times
12 the limit. Do you see that?
13 A. I agree with the math.
14 Q. And then let's do batches 27
15 and 28. 16.93. Let's do 16.93 divided by
16 .083. 203 times higher than the NDEA
17 limit. Do you see that?
18 A. Yes.
19 Q. Were you not aware that .3
20 parts per million was the threshold limit?
21 A. I just don't recall when the
22 discussion of limits from FDA occurred kind
23 of in this time frame, because it has been
24 so long.

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1 Q. Look at row 14. So it has got
2 15.29 parts per million of NDEA, right?
3 184 times the threshold for NDEA, right?
4 A. If that's what the math said, I
5 don't recall.
6 Q. And this batch also has NDMA in
7 it too. Do you see that?
8 A. Yes.
9 Q. 5.44 parts per million, right?
10 A. Yes.
11 Q. And we know the threshold for
12 NDMA, again, is .3 parts per million, so if
13 we could do 5.44 divided by .3, and that's
14 18 times the threshold limit for NDEA,
15 right, in the same batch?
16 A. Yes.
17 Q. Row 14 specifically has 184
18 times the threshold amount for NDEA and 18
19 times the threshold amount for NDMA,
20 correct?
21 A. If those were the thresholds at
22 the time, yes.
23 Q. And this is in Torrent's
24 valsartan product, right?

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1 A. I can't tell from this
2 document. These to me look like API batch
3 numbers, so this seems to be a list of API
4 batch content, but I'm missing the top of
5 the document, so.
6 Q. This is API that was used in
7 Torrent's valsartan product, right?
8 MS. NAGLE: Objection,
9 foundation.
10 THE WITNESS: I don't
11 know if this API was used in our
12 products versus just having been in
13 inventory.
14 BY MS. PENDLEY:
15 Q. Okay. Let's zoom out for a
16 second and show the whole document. Okay.
17 Do you see the Torrent logo up there, so
18 this is at least your product in some
19 capacity, right?
20 A. It is our document. That's
21 what that means.
22 Q. Okay. And it doesn't really
23 make sense that Torrent would be testing
24 somebody else's products, right?

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1 MS. NAGLE: Objection to
2 form.
3 THE WITNESS: Again,
4 when you look at the title, this is
5 valsartan API, so this is not
6 testing of a drug product.
7 BY MS. PENDLEY:
8 Q. Right. It is valsartan API
9 that Torrent used in their product, right?
10 A. No, you can't conclude that.
11 As I said, I don't know if these batches
12 were, of API were used in finished drug
13 product or whether these were just batches
14 that were in inventory awaiting use.
15 Q. Okay. But it's definitely
16 batches that Torrent purchased, right?
17 A. That is a likely conclusion,
18 yes, that these are batches that we had
19 purchased.
20 Q. Look at row 4. See for NDMA
21 here, it's 125.03 parts per million. Do
22 you see it?
23 A. Yes.
24 Q. Go to the calculator one more

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1 time. We'll do 125.03 divided by .3. So
2 416.76 times the threshold limit in this
3 batch, right?
4 A. The math is correct.
5 MS. PENDLEY: Okay. We
6 having going about an hour. Do you
7 all want to take a break?
8 MS. NAGLE: Sure.
9 MS. PENDLEY: Ten
10 minutes, is that good for you?
11 MS. NAGLE: That works.
12 MS. PENDLEY: We'll be
13 back in ten minutes.
14 THE VIDEOGRAPHER:
15 10:05, we are off the video record.
16 - - - - -
17 (A recess was taken at this time.)
18 - - - - -
19 THE VIDEOGRAPHER:
20 10:22, we are on the video record.
21 BY MS. PENDLEY:
22 Q. If you could put LP 1337 back
23 up. I'm going to show you, when I asked
24 you if this was Torrent's product or API

<p style="text-align: right;">Page 66</p> <p>1 that was used in Torrent's product, you 2 said you weren't sure if it made it all the 3 way to the finished dose drug. Do you 4 remember that? 5 A. Yes. 6 Q. Okay. So I want to show you a 7 couple of examples. I want to look at 8 row 8, and first we're going to look at the 9 levels of NDMA that are in this batch. So 10 you can see 111.72 parts per million of 11 NDMA. Do you see that? 12 A. Yes. 13 Q. So if we can divide that .3, 14 372 times over the limit, right? 15 A. I agree with the math. 16 Q. If we could also pull LP 1218. 17 Okay. If we could keep 1337 up too, so I 18 can compare batch numbers, please. Okay. 19 So looking at row 8, under column 3 is the 20 batch number on this one, 1337. Can you 21 see that batch number is AR11D0743. Do you 22 see that? 23 A. Yes. 24 Q. So this is for the one we just</p>	<p style="text-align: right;">Page 68</p> <p>1 number, seventh column, so that is Torrent 2 Pharma Limited, right? 3 A. Yes. 4 Q. And if we look at the bottom 5 half of 51 and 52 we see that same batch 6 number, the ARI11D0743, right? 7 A. Yes. 8 Q. This is showing us that that 9 API batch made it into that corresponding 10 finished good, that finished dose product, 11 right? 12 A. Yes. 13 Q. Okay. Let's look another one. 14 Let's do row 14 from LP 1337. So we 15 already did you the math on this one. This 16 was the one that had 18 times the threshold 17 amount of NDMA and 184 times the threshold 18 amount of NDEA. Do you remember that? 19 A. I don't remember the math, but 20 if that's what you say that is, that's 21 fine. 22 Q. All right. Let's look at the 23 batch number here, it's ARIIB0022. And 24 then if we go to row 70 on LP 1218, we see</p>
<p style="text-align: right;">Page 67</p> <p>1 did the math on. It has got 372 times the 2 levels of NDMA. So when we look at LP 3 1218, looking at rows 51 and 52, there's 4 the -- let me see, they're on the second 5 page. Okay. Looking at document LP 1218, 6 which is going to be Torrent Exhibit 79, we 7 see that these are finished goods. Do you 8 see that column that FG batch number, Ms. 9 Chitty? 10 A. Yes. 11 ----- 12 (Details of Finished Good Batches 13 Bates TORRENT-MDL-2875-00072916 marked 14 Torrent Exhibit 79 for 15 identification.) 16 ----- 17 BY MS. PENDLEY: 18 Q. And the FG code, do you see 19 that? 20 A. Yes. 21 Q. So these are finished goods 22 batch numbers? 23 A. Yes. 24 Q. And if we look at the TPL AR</p>	<p style="text-align: right;">Page 69</p> <p>1 that same batch number again under the TPL 2 AR number, right? 3 A. Yes. 4 Q. So we can see that that API 5 batch that 100 -- that had 18 times the 6 NDMA limit and the 184 times the NDEA limit 7 was used in Torrent's finished dose batch, 8 that one listed? 9 A. Correct. For that specific 10 batch. 11 Q. Okay let's shift gears a little 12 bit. We can take this document down. 13 Let's talk a little bit about how this 14 happened. So after about 2010, Torrent 15 started getting its API for valsartan from 16 a Chinese company called ZHP, right? 17 A. I don't recall when we started 18 purchasing from ZHP. 19 Q. Okay. But you did purchase 20 from ZHP for valsartan API, right? 21 A. Yes, at some point. 22 Q. Okay. So let's talk about how 23 Torrent came to chose ZHP as the API 24 manufacturer. We can agree that Torrent</p>

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1 wanted to find a cheap API product, right?
2 MS. NAGLE: Objection.
3 Form and foundation.
4 THE WITNESS: We're
5 always looking for multiple sources
6 of API. Price is not necessarily
7 always the main driver.
8 BY MS. PENDLEY:
9 Q. Okay. Let me see you something
10 and see what you think. Let's pull up LP
11 1047. It's previously in as Torrent
12 Exhibit 7, previously marked as Torrent
13 Exhibit 7. This is an email, if we can
14 zoom in on the top. You can see that it's
15 sent December 20, 2006. Do you see that?
16 A. Yes.
17 Q. Did you work at Torrent at this
18 point?
19 A. Yes, I did.
20 Q. Okay. But we can see you're
21 not on this email, right?
22 A. Correct.
23 Q. And based on what you told me
24 earlier, are these all Torrent India email

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1 addresses?
2 A. From what I can tell by the
3 email address, yes.
4 Q. Okay. Do you see the subject
5 line is API processing? So I want to go
6 down to the body of the email. It says
7 "API Processing," and there's a chart that
8 says "APIs identified/Need for processing."
9 And in this chart, we see valsartan on the
10 left-hand side. Are you with me?
11 A. Yes.
12 Q. It says "valsartan," and in the
13 right-hand side, it says "develop second
14 source with 60 percent price reduction."
15 Do you see that?
16 A. Yes.
17 Q. Okay. So 2006 was years before
18 Torrent actually put valsartan on the
19 market, right?
20 A. Yes.
21 Q. So they knew, Torrent India
22 knew back in 2006 that they wanted to
23 reduce the cost of valsartan's API even
24 back that, correct?

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1 MS. NAGLE: Objection.
2 Form, foundation.
3 THE WITNESS: My
4 interaction with this team mostly
5 focused more around developing a
6 second source, which is a risk
7 minimization step in manufacturing
8 in case something happens to one of
9 your sources, then you have a
10 second source.
11 BY MS. PENDLEY:
12 Q. Okay. But they didn't want
13 just any second source, you can see they
14 want a second source with 60 percent price
15 reduction, right?
16 MS. NAGLE: Objection to
17 form.
18 THE WITNESS: That is
19 what the text says and with
20 everything that we do in a given
21 business or industry, price is
22 always one of the considerations,
23 not necessarily always the biggest
24 or most important.

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1 BY MS. PENDLEY:
2 Q. Sure. So we can see that
3 60 percent price reduction, that just means
4 that something is 60 percent cheaper than
5 the source they have right now; is that
6 fair?
7 A. Yes.
8 Q. Okay. Let's look at LP 1088.
9 Another email, we'll look at the top. You
10 can see that it's, this will be -- it
11 already was marked as Torrent Exhibit 8.
12 We can see it's January 5, 2015. And this
13 is from Kelly Gegenheimer and it's a U.S.
14 email address. Who is that?
15 A. Kelly was one of our
16 salespeople in the U.S.
17 Q. Okay. How often did you work
18 with -- is Kelly a boy or a girl?
19 A. Male.
20 Q. All right. How often did you
21 work with him?
22 A. We worked together for a number
23 of years at Torrent.
24 Q. Okay. And the rest of the

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<p>1 email addresses on here, those are all 2 Torrent U.S. people as well, right? 3 A. Yes. 4 Q. Okay. You're not on this 5 email, but have you ever -- we can zoom out 6 and show her the whole thing, but have you 7 ever seen this before? 8 A. I don't recall if I've seen an 9 email from 2015 or not. 10 Q. Okay. So if we go down to the 11 bottom of the page. This is going to be 12 the first email in the chain from Sanjay 13 Gupta, and that last sentence says "We are 14 using cheaper Chinese API so our costs 15 should be very competitive." Do you see 16 that? 17 A. Yes. 18 Q. Cheaper Chinese API, that would 19 be referencing ZHP at this point, right? 20 MS. NAGLE: Objection, 21 foundation. 22 THE WITNESS: I'm not 23 sure. I think that's referencing 24 ZHP.</p>	<p>1 something is cheap, it may be low quality; 2 is that fair? 3 MS. NAGLE: Objection, 4 form. 5 THE WITNESS: That is -- 6 that could be the interpretation of 7 that phrase, yes. 8 BY MS. PENDLEY: 9 Q. And to make sure that is not 10 the case, you know, you need to be careful, 11 you need to decide if what you're 12 purchasing is worth that lower cost, right? 13 MS. NAGLE: Objection to 14 form. 15 THE WITNESS: Correct. 16 BY MS. PENDLEY: 17 Q. So in order to ensure that this 18 cheaper Chinese API is also not low quality 19 or somehow problematic, Torrent should do 20 its homework, right? 21 MS. NAGLE: Objection, 22 form. 23 THE WITNESS: Correct, 24 and there are processes in place</p>
Page 75	Page 77
<p>1 BY MS. PENDLEY: 2 Q. So who is Sanjay Gupta? 3 A. Sanjay was the CEO of the U.S. 4 company at this time. 5 Q. Okay. Do you know anybody else 6 who is on this email? 7 A. Yeah, Jim, Kelly, Chip, Noopur 8 are all sales team related for the U.S. and 9 Lokesh is the CFO for the U.S. 10 Q. Okay. So this email is the CEO 11 of U.S. telling his salespeople that we are 12 using cheaper Chinese API? 13 A. Yes. 14 Q. Which you told me is 15 referencing ZHP? 16 A. I believe it references ZHP. 17 Q. Ms. Chitty, you're familiar 18 with the idea you get what you pay for, 19 have you ever had that before? 20 A. I've heard that phrase. 21 Q. Do you know what it means? 22 A. Quite literally, you get what 23 you pay for. 24 Q. Does it mean, you know, if</p>	<p>1 for vetting any new materials that 2 we use within our -- within the 3 Torrent products to make sure that 4 they meet current standards and so 5 those, I'm sure, were followed in 6 this situation as well. 7 BY MS. PENDLEY: 8 Q. Okay. And one of those 9 procedures is inspecting the API facility, 10 right? 11 MS. NAGLE: Objection, 12 foundation. 13 THE WITNESS: I don't 14 recall the specific Torrent 15 procedure, because we were -- I 16 wasn't directly involved with that 17 type of vetting activity. I know 18 that sometimes, you do an on-site 19 visit, sometimes, you do not, 20 according to our procedures and 21 what they would allow. 22 BY MS. PENDLEY: 23 Q. Okay. Torrent as a finished 24 dose manufacturer, we can agree, probably</p>

<p style="text-align: right;">Page 78</p> <p>1 should inspect the facilities of any 2 manufacturer it's using, right? 3 MS. NAGLE: Objection. 4 Form and foundation. 5 THE WITNESS: Again, 6 that's not my decision. There are 7 industry and regulator expectations 8 and the firm requirement for an 9 on-site visit, I don't believe is 10 part of any current FDA guidance. 11 BY MS. PENDLEY: 12 Q. Okay. So how do you know 13 what's going on at those facilities if 14 nobody from Torrent ever goes there to 15 check them out? 16 MS. NAGLE: Objection to 17 form and foundation. 18 THE WITNESS: Again, 19 this is a little out of my area of 20 expertise, because I didn't 21 participate in this activity 22 directly, but I believe the team 23 does paper types of surveys and 24 research and obtains historical</p>	<p style="text-align: right;">Page 80</p> <p>1 A. They would potentially be from 2 the facility. They would potentially, I 3 know sometimes we ask for inspection 4 reports, you know, from other regulators. 5 Things along those lines. I'm sure that's 6 not an exhaustive list of the materials 7 that they would review when vetting a 8 supplier. 9 Q. So when you're asking for FDA 10 inspections from other suppliers, you mean 11 inspections that the FDA has done of 12 another facility, you would ask for those. 13 Is that what you're saying? 14 A. Potentially, yes. 15 Q. Okay. And we can agree that if 16 you don't actually send somebody to go look 17 at the facility, you would have to be 18 relying on information either from the FDA 19 or that facility, right? 20 MS. NAGLE: Objection. 21 Form and foundation. 22 THE WITNESS: I guess 23 I'm just not familiar with all of 24 the potential sources of</p>
<p style="text-align: right;">Page 79</p> <p>1 documents, for instance, from 2 sites. They would test samples, 3 for instance, things along those 4 lines. 5 BY MS. PENDLEY: 6 Q. So if nobody from Torrent or 7 somebody working for Torrent like a third 8 party ever goes and inspects these 9 facilities, Torrent would just be relying 10 on information they get from the 11 facilities; is that fair? 12 MS. NAGLE: Objection to 13 form and foundation. 14 THE WITNESS: Again, I'm 15 not intimately familiar with all 16 the details of that activity, but 17 there are procedures that dictate 18 what was allowable. 19 BY MS. PENDLEY: 20 Q. No, I know, you mentioned that 21 if you don't inspect, you would be relying 22 on testing data and other documents. So 23 would those testing data and other 24 documents be from the facility?</p>	<p style="text-align: right;">Page 81</p> <p>1 information. So that's why I'm not 2 answering yes to that question. 3 BY MS. PENDLEY: 4 Q. Okay. Let's break it down a 5 little more simple then. If Torrent is not 6 witnessing the facility for themselves, 7 they, obviously, have to rely on somebody 8 else to give them information, right? 9 A. That seems reasonable, yes. 10 Q. Okay. We can agree that the 11 point of an inspection had one been done 12 would be to kind of supervise the facility? 13 MS. NAGLE: Objection. 14 Form and foundation. 15 THE WITNESS: Was that a 16 question, I'm sorry? 17 BY MS. PENDLEY: 18 Q. Yes. 19 A. You used the word "supervise," 20 so no. Our intent in observing a potential 21 vendor is not to supervise the facility. 22 Q. What is the point of an 23 inspection? 24 A. To probably observe the</p>

<p style="text-align: right;">Page 82</p> <p>1 facility.</p> <p>2 Q. Okay. What are you observing</p> <p>3 for? Are you looking for problems?</p> <p>4 A. You are looking for, for</p> <p>5 instance, what the facility, how the</p> <p>6 facility is structured. How they're</p> <p>7 operating. I believe when people do</p> <p>8 on-site inspections, they tend to review</p> <p>9 procedures, things like that.</p> <p>10 Q. Okay. Is it fair to say that</p> <p>11 when you're doing an inspection, you're</p> <p>12 trying to ensure that the facility is</p> <p>13 operating in the way that you would want it</p> <p>14 to?</p> <p>15 MS. NAGLE: Objection.</p> <p>16 Form and foundation.</p> <p>17 THE WITNESS: In a</p> <p>18 general sense, I think that's a</p> <p>19 reasonable expectation.</p> <p>20 BY MS. PENDLEY:</p> <p>21 Q. Okay. And generally, the way</p> <p>22 you would want the facility to operate is</p> <p>23 in a way that protects patient safety,</p> <p>24 right?</p>	<p style="text-align: right;">Page 84</p> <p>1 Form and foundation.</p> <p>2 THE WITNESS: I would</p> <p>3 assume so.</p> <p>4 BY MS. PENDLEY:</p> <p>5 Q. Okay. It's important that when</p> <p>6 they are there, they're looking for the</p> <p>7 appropriate information; is that fair?</p> <p>8 MS. NAGLE: Objection.</p> <p>9 Form and foundation.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. PENDLEY:</p> <p>12 Q. If the inspector doesn't know</p> <p>13 what to look for, it would make sense that</p> <p>14 they would not be giving Torrent accurate</p> <p>15 information, right?</p> <p>16 MS. NAGLE: Objection.</p> <p>17 Form and foundation.</p> <p>18 THE WITNESS: And it's</p> <p>19 very theoretical. I mean, we're</p> <p>20 talking in theoretical scenarios</p> <p>21 about something I am not intimately</p> <p>22 familiar with, so.</p> <p>23 BY MS. PENDLEY:</p> <p>24 Q. Okay. If you don't know that</p>
<p style="text-align: right;">Page 83</p> <p>1 MS. NAGLE: Objection.</p> <p>2 Form and foundation.</p> <p>3 THE WITNESS: You would</p> <p>4 want the facility to operate in</p> <p>5 compliance with their own</p> <p>6 procedures as well as regulator</p> <p>7 expectations.</p> <p>8 BY MS. PENDLEY:</p> <p>9 Q. So protecting patient safety is</p> <p>10 not factored into the equation there?</p> <p>11 MS. NAGLE: Objection.</p> <p>12 Form and foundation.</p> <p>13 THE WITNESS: The</p> <p>14 regulations that are in place are</p> <p>15 designed to ensure that things are</p> <p>16 done properly with the end patient</p> <p>17 safety in mind.</p> <p>18 BY MS. PENDLEY:</p> <p>19 Q. Okay. We can agree that when</p> <p>20 conducting an inspection, it's important</p> <p>21 that the inspector would know what to look</p> <p>22 for or be educated in the proper</p> <p>23 procedures, right?</p> <p>24 MS. NAGLE: Objection.</p>	<p style="text-align: right;">Page 85</p> <p>1 the inspector is properly trained, how do</p> <p>2 you know that you're going to get proper</p> <p>3 information back from that inspection?</p> <p>4 MS. NAGLE: Objection.</p> <p>5 Form and foundation.</p> <p>6 THE WITNESS: So</p> <p>7 typically, if we're hiring or</p> <p>8 working with an inspector, part of</p> <p>9 the process of using that inspector</p> <p>10 should be to confirm that they have</p> <p>11 the proper background to do the</p> <p>12 proper job that we expect them to</p> <p>13 do.</p> <p>14 BY MS. PENDLEY:</p> <p>15 Q. Okay. And it would be</p> <p>16 important that they had that training,</p> <p>17 right?</p> <p>18 MS. NAGLE: Objection.</p> <p>19 Form and foundation.</p> <p>20 THE WITNESS: I don't</p> <p>21 know if I agree with the word</p> <p>22 "training," but the proper</p> <p>23 background and knowledge.</p> <p>24</p>

<p>Page 86</p> <p>1 BY MS. PENDLEY: 2 Q. Okay, let's pull up LP 1191. 3 This is previously marked as Torrent 4 Exhibit 9. 5 All right. We can see from the 6 first page, that this was an inspection 7 that took place in May 2016. Do you see 8 that? 9 A. Yes, okay. 10 Q. All right. And then the 11 facility that was inspected is the Indrad 12 facility kind of up at the top? 13 A. Correct. 14 Q. That's in India, right? 15 A. Yes. 16 Q. Okay. If we can go to what's 17 marked as page 5. Okay. Do you see that 18 where it says Post-Inspectional 19 Correspondence should be addressed to the 20 following individuals." And then you are 21 the second name listed. Do you see that? 22 A. Correct. 23 Q. So does this mean that you 24 would get a copy of all the FDA inspections</p>	<p>Page 88</p> <p>1 A. I don't recall. It was from 2 2016, right? 3 Q. Yes. 4 A. Yeah, I don't recall 5 specifically. 6 Q. Okay. Let's look through it a 7 little bit. If we could go to the next 8 page. Right there at the top, it lists 9 some people that were at this facility and 10 the first name is Dr. Niles Trivedi, the 11 general manager of quality. Have you 12 worked with him before? 13 A. Yes. 14 Q. Okay. So we can see that he's 15 overall responsible for the quality of the 16 Indrad site and was present throughout the 17 inspection. 18 Let's go to page 11. And this 19 first paragraph under supplier 20 qualifications, if we could look at that. 21 Okay. So this says "The firm used a 22 third-party auditor to conduct a site 23 audit/vendor qualification without training 24 the third-party auditor or verifying the</p>
<p>Page 87</p> <p>1 of Torrent facilities or correspondence 2 that comes after the fact? 3 A. I'm sorry, can you repeat the 4 first part of your question? 5 Q. Yes. Do you receive copies of 6 FDA inspections of Torrent facilities? 7 A. Yes. 8 Q. Okay. All of them? 9 A. I believe I normally receive 10 all of them. Sometimes, the notice does go 11 directly to the head of the site rather 12 than me. I normally get a courtesy copy, 13 because I was their U.S. agent. 14 Q. Okay. So does that include the 15 inspection itself as well as any 483s? 16 A. When you say the inspection, so 17 the notice of inspection? 18 Q. Yes. 19 A. Typically, I saw most of those. 20 Again, occasionally, I think they would go 21 directly to the site, so I may not have 22 seen all of them. 23 Q. Okay. Do you know if you've 24 seen this inspection before?</p>	<p>Page 89</p> <p>1 third-party auditor's vendor qualification 2 program." Do you see that? 3 A. Yes. 4 Q. It goes on to say "The audit 5 report for the Valsartan API manufacturer 6 was written by a third-party auditor, Jian 7 Yang of Dragonfarm Co. Limited." So at 8 this point in 2016, the valsartan API 9 manufacturer was ZHP, right? 10 A. I don't recall when we started 11 using the ZHP API. 12 Q. Okay. So this says that -- are 13 you familiar with Dragonfarm? Have you 14 heard of that company before? 15 A. No. 16 Q. Okay. Were you aware that 17 Torrent used a third party to inspect the 18 valsartan API manufacturer? 19 A. I don't recall off the top of 20 my head, but according to this document, 21 which I probably saw at some point, that's 22 what it says here. 23 Q. Who or what department at 24 Torrent makes the decision to use a</p>

<p>Page 90</p> <p>1 third-party auditor versus a direct Torrent 2 employee? 3 A. I'm not sure specifically. 4 Quality is involved in that, but I'm not 5 sure who all the decision-makers would be 6 for that type of vendor decision. 7 Q. Do you think the head of 8 quality would be involved in that? 9 MS. NAGLE: Objection. 10 Form and foundation. 11 THE WITNESS: Yeah, I'm 12 not sure. 13 BY MS. PENDLEY: 14 Q. Okay. All right. Let's keep 15 reading, it says "I asked Dr. N. Trivedi if 16 the firm verified or qualified this 17 vendor's supplier qualification program." 18 And it says "Dr. Trivedi stated no." So 19 what that's saying is that Torrent did not 20 verify or qualify this vendor's supplier 21 qualification program, right? 22 A. That is what that sentence 23 says. 24 Q. All right. And then the next</p> <p>Page 91</p> <p>1 sentence says "I asked Dr. Trivedi if the 2 firm trained this vendor to follow their 3 vendor qualification program and procedures 4 and Dr. Trivedi stated no." So that means 5 Torrent did not train this auditor to 6 follow their procedures. Do you see that? 7 A. That's what it says. 8 Q. So if Torrent isn't training 9 their auditor or verifying its procedures, 10 how can Torrent ensure that the inspection 11 was accurate? 12 MS. NAGLE: Objection. 13 Form and foundation. 14 THE WITNESS: Yeah, 15 again, this isn't something I was 16 involved in from a decision-making 17 or a day-to-day standpoint, so I 18 don't really have any background on 19 the specific situation. 20 BY MS. PENDLEY: 21 Q. I understand that. Just from a 22 common sense standpoint, I know you have 23 been doing regulatory a long time, what do 24 you think about sending an inspector that's</p>	<p>Page 92</p> <p>1 not properly trained to do an inspection? 2 MS. NAGLE: Objection. 3 Form and foundation. 4 THE WITNESS: I'm not 5 sure if not properly trained is the 6 right phrase. It seems like there 7 were maybe a couple of steps that 8 we should have, additional steps 9 that we should have taken in the 10 process of vetting that vendor. 11 BY MS. PENDLEY: 12 Q. I want to take you back, 13 because I mean, training is the issue here. 14 It literally says Dr. Trivedi asked the 15 firm, asked if the firm trained the vendor 16 and the answer was no. Do you see that? 17 A. I see it. 18 Q. Okay. 19 A. I'm not sure that it's required 20 that we necessarily train the firm. Again, 21 this is a little outside my everyday area 22 of expertise. 23 Q. Okay. Ms. Chitty, say you were 24 going to send somebody to go do your job on</p> <p>Page 93</p> <p>1 your behalf, would it make sense that you 2 train that person to do your job for you? 3 MS. NAGLE: Objection to 4 form. 5 THE WITNESS: Not if 6 they were otherwise properly 7 qualified and experienced. 8 BY MS. PENDLEY: 9 Q. Okay. If Torrent doesn't 10 properly train their auditors, how do they 11 know they're properly trained? 12 MS. NAGLE: Objection. 13 Form and foundation. 14 THE WITNESS: Yeah, and 15 again, I didn't do this, you know, 16 hands-on, so I assume there was 17 some sort of checking that went on, 18 but I can't really speak to the 19 details of that. 20 BY MS. PENDLEY: 21 Q. Okay. So you don't know for 22 sure how Torrent trains their auditors at 23 all? 24 A. No.</p>
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<p style="text-align: right;">Page 94</p> <p>1 Q. Okay. Let's go to the next 2 paragraph, because it seems like the FDA 3 has similar concerns that I'm asking of 4 you. It says "I asked Dr. Trivedi if the 5 firm doesn't train the auditor in the 6 firm's vendor audit program or verify the 7 third-party auditor's vendor qualification 8 program if the firm can be sure that the 9 third party auditor conducted the audit in 10 a manner satisfactory to the firm." Do you 11 see that? 12 A. Yes. 13 Q. And Dr. Trivedi stated no, 14 right? 15 A. That's what it says. 16 Q. So the FDA inspector is asking 17 a Torrent employee if you guys don't train 18 your auditor, how do you know it's 19 conducted in a satisfactory manner, right? 20 A. That seems to be the question 21 here. 22 Q. And Torrent's employee said no, 23 as in no, we can't ensure that it's 24 conducted in a satisfactory manner, right?</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. Okay. I promise I'm not making 2 it up. I'm reading what's on my copy. So 3 it goes on to say, "I asked Dr. Trivedi if 4 the firm trained Jenny Yang to conduct site 5 inspection vendor audits according to their 6 procedures. Dr. Trivedi stated no." So 7 once again, we've got a more specific 8 example, Torrent is confirming they did not 9 train their inspectors specifically to 10 inspect ZHP's API facility. Okay? 11 A. It talks about training them to 12 our Torrent procedures. 13 Q. Right. And that didn't happen, 14 right? 15 A. According to this, no. 16 Q. Okay. It says "I asked Dr. 17 Trivedi if the firm had verified the vendor 18 qualification procedure followed by Jenny 19 Yang. And Dr. Trivedi stated no." Right? 20 A. Again, I can't really confirm 21 that from this version, but that somewhat 22 looks like what's there on the document. 23 Q. Okay. So while Jenny Yang may 24 have been trained by somebody, whatever</p>
<p style="text-align: right;">Page 95</p> <p>1 A. That's what the document 2 details. 3 Q. Okay. Let's go to page, I 4 think it's 29, so this copy that we got is 5 a little bit hard to read. Okay. It's 6 even worse for you, so I'll read part of it 7 to you. There's a paragraph here about 8 halfway down. Starting on the left-hand 9 side it says, "Form No. CQA-037/03 dated 10 November 11, 2014, is the returned 11 self-completed questionnaire for the 12 third-party auditor the firm used to 13 conduct a site inspection/vendor audit of 14 the API manufacturer," and it's the Chinese 15 name for ZHP, okay. "ZHP of Valsartan USP 16 in Linhai, China. The response recorded," 17 two words I can't read, "is N/A." Okay. 18 So we can see that they are talking about 19 the auditor that audited ZHP, your API 20 manufacturer, right? 21 A. I mean, I can't really make 22 much out of that middle part there, 23 unfortunately, so I'm, you know, it's 24 something related to ZHP.</p>	<p style="text-align: right;">Page 97</p> <p>1 procedure she was using was not verified by 2 Torrent, right? 3 A. That seems to be what this is 4 saying. 5 Q. And you don't know who at 6 Torrent during this time frame would be 7 responsible for training its auditors? 8 A. No, I'm not specifically sure 9 which group or person handled that. 10 Q. Okay. Let's shift gears a 11 little bit and talk about your role in this 12 case. If we could pull up LP 1453. This 13 will be Torrent Exhibit 80. 14 Now, Ms. Chitty, you've seen 15 this before, right? 16 A. Yes. 17 Q. And this is your CV? 18 A. Correct. 19 ----- 20 (Curriculum Vitae marked Torrent 21 Exhibit 80 for identification.) 22 ----- 23 BY MS. PENDLEY: 24 Q. In the beginning here at this</p>

<p style="text-align: right;">Page 98</p> <p>1 top paragraph, it says "Over 25 years' 2 experience as a pharmaceutical scientist, 3 regulatory affairs professional and 4 strategic leader within the pharmaceutical 5 industry." It goes on to say "Significant 6 contributor to the successful global drug 7 development and approval in multiple 8 therapeutic areas for a \$400 million 9 company." At the end, it says you were a 10 "Senior decision maker responsible for 11 identifying market potential, advising on 12 risks and identifying potentially 13 regulatory hurdles while providing 14 financially viable solutions." Do you see 15 that? 16 A. Yes. 17 Q. All right. And if we go down 18 to your job history, you're currently 19 working at PRA Health Sciences? 20 A. Correct. 21 Q. Tell me a little bit about your 22 job there. 23 A. Currently, I oversee a 24 regulatory strategy team within PRA. PRA</p>	<p style="text-align: right;">Page 100</p> <p>1 than your regulatory affairs position? 2 A. The strategy and scientific 3 affairs component kind of included 4 oversight of regulatory as well as 5 additional activities such as product 6 selection that we were targeting for 7 development. I had a team of people, 8 project managers in projects that were in 9 development for Torrent, kind of a subset 10 of their portfolio that I oversaw the local 11 development of in the U.S. and I had some 12 employees that project managed that work. 13 Q. Okay. So I want to focus on a 14 couple of things here, so under VP of 15 regulatory affairs, that first bullet says 16 "Directed all U.S. regulatory functions 17 relating to U.S. development and commercial 18 activities," and it goes on to say 19 "included oversight of a team of four 20 regulatory affairs individuals." Who are 21 those people? 22 A. I don't remember necessarily at 23 the time. I know that Susan Perry was 24 working for me in this time frame. I think</p>
<p style="text-align: right;">Page 99</p> <p>1 is a contract research organization, so we 2 support a variety of clients in a broad 3 variety of ways. 4 Q. Okay. Are you being paid for 5 your time here today, Ms. Chitty? 6 A. No. 7 Q. So you currently work for what 8 sounds like a consulting company. Is it 9 fair to say you advise other companies on 10 regulatory strategies? 11 A. Correct, my group does. 12 Q. Okay. And so prior to that, 13 you worked at Torrent, right? 14 A. Yes. 15 Q. If you go to page 2. So it 16 looks like you worked at Torrent for about 17 14 years; is that right? 18 A. Correct. 19 Q. You've had various titles, 20 including director of regulatory affairs, 21 vice president of regulatory affairs, and 22 then vice president of strategy and 23 scientific affairs. So how is your VP in 24 strategy and scientific affairs different</p>	<p style="text-align: right;">Page 101</p> <p>1 Brijesh Patel was working for me and I 2 believe I had a person in Canada who was 3 called Dagmar Nelson. I don't remember who 4 the fourth person is. 5 Q. All right. And then you say 6 you're the U.S. agent for Torrent 7 Pharmaceuticals Limited for all FDA 8 communications. Do you see that? 9 A. Yes. 10 Q. So does that mean that all 11 communication from the FDA would be sent 12 through you in some capacity? 13 A. Typically, it should be. 14 Again, occasionally, there may have been 15 one-off communications that I was not 16 included in, but I saw the majority of 17 things coming into the company. 18 Q. Okay. Is that for all drug 19 products that Torrent was involved with? 20 A. Correct. 21 Q. Okay. Under director of 22 regulatory affairs, you say you mentor the 23 regulatory affairs group in India regarding 24 U.S. requirements. So you've mentioned</p>

<p>Page 102</p> <p>1 some email addresses to me during this, so 2 we know there's an Indian and an U.S. 3 division of Torrent. How often would you 4 and your U.S. department meet with somebody 5 in the Indian division? 6 A. Meet, we would probably 7 communicate every day. 8 Q. Okay. Are you responsible for 9 updating India on any particular U.S. 10 regulatory issues? 11 A. Typically, if I became aware of 12 new guidelines, new information coming out, 13 yeah, we would share that with our team in 14 India. 15 Q. Okay. So are you supposed to 16 update them on new things that are 17 happening in the U.S.? 18 A. I think that's a fair 19 characterization, yeah. 20 Q. Okay. So which division, U.S. 21 or India, actually conducts testing of the 22 drugs that you guys sell? 23 A. Our teams in India do that 24 testing.</p> <p>Page 103</p> <p>1 Q. Is that true for valsartan too? 2 A. As far as I can remember, yes, 3 I believe it was solely tested in India. 4 Q. Was that true for the API and 5 the finished dose? 6 A. Yes, as far as I can remember. 7 Q. So once that testing is 8 conducted, any relevant testing would 9 obviously have to be sent from India to the 10 U.S., right? 11 A. No, because on a routine basis, 12 the testing that we do is not something 13 that would be shared with me nor shared 14 with the FDA. You know, it's kind of 15 the -- just the common business. You save 16 those records at your manufacturing 17 facility. You don't necessarily share them 18 with FDA or people, other people within the 19 company outside of manufacturing. 20 Q. Okay. So what I mean is if you 21 were to receive testing results about a 22 drug, it would have had to have come from 23 India; is that right? 24 A. If I were to receive testing</p>	<p>Page 104</p> <p>1 results. If we were doing the testing, it 2 would have come from India. There are 3 certain, I would say, situations where 4 sometimes the API supplier, you know, might 5 have been testing something. There are 6 also, I think I can remember times when FDA 7 requested samples from us, as they 8 routinely sometimes do, just to verify 9 compliance. So it's possible we might have 10 gotten results back from FDA as well. So 11 it could have come from various sources, 12 but it, to my knowledge, was not coming 13 from Torrent U.S. We had no capabilities 14 to test. 15 Q. Okay. So if you were receiving 16 testing that Torrent was doing, it would be 17 Torrent India's testing? 18 A. Correct. 19 Q. Okay. And so we've seen that 20 Torrent India sends you in the U.S. certain 21 documents like that Health Hazard 22 Evaluation, like the testing levels, so 23 when Torrent sends you documents like that, 24 are you able to actually make any changes</p> <p>Page 105</p> <p>1 or edits or do you have to accept it as 2 it's sent to you? 3 A. In most cases, I was also a 4 reviewer to kind of, you know, apply my 5 U.S.-specific knowledge in guiding them on 6 certain relevant issues. 7 Q. So if you make edits to a 8 document, do those have to be approved by 9 Torrent India or are you allowed to send it 10 out as you've made changes to it? 11 A. It depends on what it is. For 12 instance, if they were to send me a 13 technical document, I may make suggestions, 14 but that would probably, for instance, have 15 to go back to the team in India to decide 16 whether they agree or disagree with 17 changes. And then there's, you know, 18 certain people who probably sign off on 19 specific things, so that would be the 20 decision of the final person or group 21 responsible for whichever document it may 22 be. 23 Q. What group is typically 24 responsible for approving documents that</p>
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1 you would edit?

2 A. That's a really broad question.

3 I mean, I would see a lot of different

4 documents. So it's a very broad potential

5 group of people that may be responsible for

6 them.

7 Q. All right. Let's talk about a

8 document, say, like the Health Hazard

9 Evaluation that we looked at earlier where

10 you guys are discussing the dangers of

11 NDMA. If you were to make an edit to a

12 document like that, who would have to

13 approve it?

14 A. The medical team that was

15 responsible for producing the document.

16 Q. So what communication, if any,

17 do you have about Torrent Pharmaceuticals'

18 regulatory issues, you know, how often do

19 you relay that information to India?

20 MS. NAGLE: Objection to

21 form.

22 THE WITNESS: Yeah, I'm

23 not sure I understand the question.

24

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1 BY MS. PENDLEY:

2 Q. If the FDA comes to you with a

3 problem about a drug that Torrent sells, do

4 you always relay that information to

5 Torrent India?

6 A. Yes.

7 Q. Okay. Torrent sells drugs in

8 other countries aside from the U.S. and

9 India, right?

10 A. Correct.

11 Q. Do those other countries kind

12 of report back to India in the same way

13 that you do in the U.S.?

14 MS. NAGLE: Objection,

15 foundation.

16 THE WITNESS: I don't

17 know the specifics, because I

18 wasn't involved, but I believe that

19 there was a similar relationship

20 for the other markets --

21 BY MS. PENDLEY:

22 Q. Okay.

23 A. -- as to what we had in the

24 U.S.

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1 Q. Okay. So Torrent India kind of

2 supervises the Torrent facilities in other

3 countries; is that fair?

4 MS. NAGLE: Objection.

5 Form and foundation.

6 THE WITNESS: I'm not

7 sure if supervises is the right

8 word. We have a relationship and

9 they are experts in certain areas,

10 so they, you know, they control

11 certain aspects of the business, I

12 will say.

13 BY MS. PENDLEY:

14 Q. All right. Particularly on

15 this case, was it Torrent U.S. or Torrent

16 India who made the decision to recall the

17 product?

18 A. A recall decision is by

19 procedure the decision of the quality unit

20 in India.

21 Q. Okay. Okay. So you understand

22 that in order to ensure that drug

23 manufacturers are selling quality drugs,

24 federal regulations apply to manufacturers

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1 that sell drugs in the United States,

2 right?

3 MS. NAGLE: Objection.

4 Form and foundation.

5 THE WITNESS: Correct, I

6 agree.

7 BY MS. PENDLEY:

8 Q. So Torrent sells drugs in the

9 U.S., so Torrent has to abide by these

10 regulations; is that fair?

11 A. Correct.

12 Q. And you're familiar with these

13 regulations due to your regulatory affairs

14 experience?

15 A. Yes.

16 Q. So you understand that under

17 federal law, pharmaceutical drugs must be

18 manufactured in accordance with what's

19 called good manufacturing practices or

20 CGMP, right?

21 A. Correct.

22 Q. You know that CGMP sets a

23 minimum standard, meaning companies can do

24 that more than that, they just can't do

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1 less?

2 A. Correct.

3 Q. If a drug is manufactured in a

4 way that violates CPMG, it is considered

5 adulterated, right?

6 A. Correct.

7 Q. So CGMPs require manufacturers

8 to ensure that their drug meets, among

9 other things, four standards of identity,

10 strength, quality, and purity, right?

11 MS. NAGLE: Objection to

12 form.

13 THE WITNESS: Correct.

14 BY MS. PENDLEY:

15 Q. Those things help ensure that a

16 drug is safe, right?

17 MS. NAGLE: Objection,

18 form.

19 THE WITNESS: Correct.

20 BY MS. PENDLEY:

21 Q. If Torrent was not prepared to

22 ensure that its drugs met those four

23 standards, that would be a problem, right?

24 MS. NAGLE: Objection to

Page 111

1 form.

2 THE VIDEOGRAPHER: I'm

3 sorry for the interruption. Your

4 objections are barely audible. If

5 you could speak up little louder or

6 get a little closer to the

7 microphone, that would be great.

8 MS. NAGLE: Sure. Sorry

9 about that.

10 THE VIDEOGRAPHER: Thank

11 you.

12 THE WITNESS: Sorry, can

13 you repeat that question, please?

14 BY MS. PENDLEY:

15 Q. Yeah. If Torrent was not

16 prepared to ensure that its drugs met those

17 four standards, identity, strength,

18 quality, and purity, that would be a

19 problem, right?

20 MS. NAGLE: Same

21 objection.

22 THE WITNESS: Torrent

23 was meeting those standards for the

24 most part.

Page 112

1 BY MS. PENDLEY:

2 Q. And if they weren't, that drug

3 would be adulterated, right?

4 MS. NAGLE: Objection,

5 form.

6 THE WITNESS: Correct.

7 BY MS. PENDLEY:

8 Q. And if a drug is adulterated,

9 it cannot be sold?

10 A. Correct.

11 Q. So it's fair to say that

12 Torrent should not be able to sell those

13 drugs until those standards are met, right?

14 A. Torrent must meet the standards

15 that are in place at the time, correct,

16 before marketing a drug.

17 Q. Okay. Let's look at LP 1055.

18 This was previously marked as Torrent

19 Exhibit 10. And look at the first page.

20 You can see this is an inspection that took

21 place in April 2017, again, at the Indrad

22 facility in India. Have you seen this

23 inspection before?

24 A. I don't recall specifically,

Page 113

1 but I probably have seen this.

2 Q. Okay. Let's go to what's

3 marked as page 2. Second paragraph here it

4 says "A four-item FDA 483, Inspectional

5 Observations were issued for," and it lists

6 four things. The first one, "the

7 responsibilities and procedures applicable

8 to the Quality Unit are not fully

9 followed." And the fourth thing says

10 "laboratory controls do not include the

11 establishment of scientifically sound and

12 appropriate test procedures designed to

13 assure that drug products conform to

14 appropriate standards of identity,

15 strength, quality, and purity." Do you see

16 that?

17 A. Yes.

18 Q. So this is saying -- well, one,

19 to back up, those are the same four things

20 you told me about earlier, right, those

21 CGMP standards?

22 A. The identity, strength,

23 quality, purity, yes.

24 Q. Okay. And you told me we have

<p>Page 114</p> <p>1 to have the identity, strength, quality, 2 and purity standards met in order to sell a 3 drug, correct? 4 A. Yes. 5 Q. So we can see that in 2017, 6 this inspector notated that Torrent did not 7 have the proper controls to ensure its 8 drugs met those standards, right? 9 A. So I think it's important to 10 understand that the phrasing of these types 11 of findings and the language that's used in 12 the reports has to kind of hearken back to 13 the language of the regulations. So the 14 phrasing that is here is kind of very 15 specific and limited when they refer to 16 what kind of potential improvements need to 17 be made at a facility. 18 You know, you also see on that 19 same page, that this inspection was 20 classified as a voluntary action indicated 21 by FDA, which means it did not raise to a 22 very significant level in the regulator's 23 mind. And that the responses that we had 24 made to these items that were brought to</p> <p>Page 115</p> <p>1 our attention had been adequately 2 addressed. 3 Q. That's all fine, but I'm going 4 to direct you back to my question. My 5 question, it's a simple yes or no, at this 6 point, the inspector indicated that Torrent 7 did not have the proper controls to ensure 8 identity, strength, quality, and purity, 9 correct? 10 A. Specifically, laboratory 11 controls in relation to whatever the 12 specifically identified product was. 13 Q. Okay. So you told me earlier 14 that Torrent was required to submit an ANDA 15 in order to put valsartan on the market, 16 right? 17 A. I don't remember if I said 18 that, but that is correct. They are 19 required to submit an abbreviated 20 application to get a drug approved. 21 Q. And in that ANDA, you know, in 22 the submission as a whole, you have to show 23 that the drug does meet the strength, 24 identity, quality, and purity standards</p>	<p>Page 116</p> <p>1 that we've talked about, right? 2 A. Correct. 3 Q. So the FDA actually allows 4 manufacturers like Torrent to rely on other 5 drug manufacturers' drug master files in 6 their ANDA submission, right? 7 A. We reference API manufacturer 8 drug master files, not other finished 9 product master files. 10 Q. Okay. So just API. And here, 11 Torrent did rely on ZHP's DMF for their 12 API, right? 13 A. For at least one API source. I 14 believe there was a second one that was 15 originally filed in the ANDA. 16 Q. Okay. And so we can agree, 17 it's ultimately Torrent's ANDA submission 18 that gives Torrent approval to sell the 19 drug, right? 20 A. Correct. 21 Q. So meaning if their ANDA, 22 Torrent's ANDA is not approved, Torrent 23 can't sell the drug yet? 24 A. Correct.</p> <p>Page 117</p> <p>1 Q. Since the DMF is contained or 2 cited back to in the ANDA, Torrent needs to 3 make sure that the information in the DMF 4 is correct, to the extent that it can? 5 MS. NAGLE: Objection, 6 form. 7 THE WITNESS: I don't 8 know if correct is the proper word. 9 They need to be comfortable that 10 the information that we are allowed 11 to see from the DMF, because we 12 don't get to see everything, is 13 consistent with current guidelines. 14 BY MS. PENDLEY: 15 Q. Okay. So you mentioned you 16 don't get to see the whole DMF. What parts 17 or what types of information does Torrent 18 get to see of an API supplier's DMF? 19 A. It varies a little bit supplier 20 to supplier. But there's always an open 21 part that should summarize at a high level 22 the steps that go into making the API, the 23 ingredients that are used, and the final 24 specification and testing that they do on</p>
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<p style="text-align: right;">Page 118</p> <p>1 the final API product.</p> <p>2 Q. Okay. So when Torrent made the</p> <p>3 decision to include ZHP's DMF in the ANDAs</p> <p>4 for valsartan, did anybody at Torrent India</p> <p>5 actually review the DMF or whatever</p> <p>6 information they were allowed to do?</p> <p>7 A. It's a standard part of the</p> <p>8 procurement process, not something I was</p> <p>9 involved in, but I would expect that, yes,</p> <p>10 someone had reviewed the open part of the</p> <p>11 ZHP DMF.</p> <p>12 Q. Do you know if anybody at</p> <p>13 Torrent U.S. reviewed the DMF?</p> <p>14 A. I don't recall.</p> <p>15 Q. If there were to be a</p> <p>16 regulatory issue with the DMF, meaning the</p> <p>17 FDA found a problem with it, would Torrent</p> <p>18 be notified?</p> <p>19 A. Typically, yes. As part of our</p> <p>20 ANDA submission, when they are reviewing</p> <p>21 the quality section, we would be notified</p> <p>22 that there were questions and deficiencies</p> <p>23 ongoing relating to the DMF.</p> <p>24 Q. When you say "we would be</p>	<p style="text-align: right;">Page 120</p> <p>1 it has got the date on it, I believe it</p> <p>2 says December 2010.</p> <p>3 A. Yes.</p> <p>4 Q. And then it is attention to</p> <p>5 you, so this was sent directly to you; is</p> <p>6 that right?</p> <p>7 A. Yes, it appears so.</p> <p>8 Q. Okay. And down kind of the</p> <p>9 middle here it says "The Division of</p> <p>10 Chemistry has completed its review of the</p> <p>11 submissions referenced above and has</p> <p>12 identified deficiencies." Look at the next</p> <p>13 page. Under A where it says deficiencies,</p> <p>14 I want to look at number one. It says the</p> <p>15 "Drug Master File 23491 was reviewed and</p> <p>16 found to be deficient." So that's ZHP's</p> <p>17 DMF that's being referenced right here,</p> <p>18 right?</p> <p>19 A. I do not know their DMF</p> <p>20 numbers, so I'm not sure which API supplier</p> <p>21 that DMF is from.</p> <p>22 Q. Okay. Let's pull up LP 1216</p> <p>23 really quick and we'll come back to this.</p> <p>24 This will be Torrent Exhibit 82.</p>
<p style="text-align: right;">Page 119</p> <p>1 notified," is that Torrent U.S. or Torrent</p> <p>2 India or both?</p> <p>3 A. Both. The applicant for our</p> <p>4 drugs was always Torrent India. I, as</p> <p>5 their U.S. agent, was typically the first</p> <p>6 point of contact on that type of</p> <p>7 information.</p> <p>8 Q. So had you or anyone else that</p> <p>9 you know of at Torrent U.S. ever been</p> <p>10 notified of a regulatory issue with ZHP's</p> <p>11 DMF?</p> <p>12 A. I don't recall. I'm sure there</p> <p>13 are letters and documents that could detail</p> <p>14 that.</p> <p>15 Q. Okay. Let's look at LP 1393.</p> <p>16 This will be marked as Torrent Exhibit 81.</p> <p>17 -----</p> <p>18 (Quality Deficient - Minor Letter</p> <p>19 Bates TORRENT-MDL2875-00009022 marked</p> <p>20 Torrent Exhibit 81 for</p> <p>21 identification.)</p> <p>22 -----</p> <p>23 BY MS. PENDLEY:</p> <p>24 Q. You can see up in the top left,</p>	<p style="text-align: right;">Page 121</p> <p>1 -----</p> <p>2 (Email String Bates</p> <p>3 TORRENT-MDL2875-00010178 to 179 marked</p> <p>4 Torrent Exhibit 82 for</p> <p>5 identification.)</p> <p>6 -----</p> <p>7 BY MS. PENDLEY:</p> <p>8 Q. And this email in the middle</p> <p>9 the email is Dr. Brijesh Patel. It says</p> <p>10 "Dear Dawn," and then later it says "Please</p> <p>11 note the DMF holder ZHP has filed amendment</p> <p>12 to DMF No. 23491." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So the ZHP's DMF number</p> <p>15 for valsartan is 23491 based on this email?</p> <p>16 A. Correct.</p> <p>17 Q. Keeping that in mind, let's go</p> <p>18 back to 1393. Go back to the page we were</p> <p>19 looking at. Next page. Okay. So drug</p> <p>20 master file 23491, that would be</p> <p>21 referencing ZHP's DMF, right?</p> <p>22 A. Yes.</p> <p>23 Q. So in 2010, the FDA found their</p> <p>24 DMF to be deficient, right?</p>

Page 122

1 A. Yes.

2 Q. So when something like this

3 happens, does the FDA inform Torrent of why

4 the DMF is deficient?

5 A. No, that's proprietary

6 information, so they communicate directly

7 with the DMF holder.

8 Q. Okay. So nobody ever sees the

9 actual deficiency notice or whatever you

10 want to call it that's sent to ZHP?

11 A. It's not provided to us from

12 FDA. A lot of times we would reach out

13 then to the DMF holder to try and

14 understand specifics of the deficiency.

15 Sometimes, companies will share them,

16 sometimes, they will not.

17 Q. I know it has been a while, but

18 do you know if anybody at Torrent reached

19 out to ZHP about this deficiency?

20 A. Yeah, I don't remember.

21 Q. All right. Okay. But this

22 would not be information that's coming from

23 the FDA, you would get the reason for the

24 deficiency directly from ZHP; is that fair?

Page 123

1 A. Correct.

2 Q. So you were not made aware that

3 ZHP's DMF was deficient for the ability to

4 perform tertiary amines, right?

5 A. Not via the FDA, no.

6 Q. Okay. And you do understand

7 that tertiary amines are considered a

8 potentially significant precursor for

9 nitrosamine formation. Are you familiar

10 with that idea?

11 A. I'm familiar with the term.

12 I'm not sure that the NDMA comes via that

13 pathway or is considered that type of

14 product, but --

15 Q. So if Torrent was informed that

16 ZHP's DMF contained information about the

17 potential to form tertiary amines, is that

18 something Torrent would have looked into,

19 do you think?

20 MS. NAGLE: Objection to

21 form.

22 THE WITNESS: Sorry.

23 Brittney, we couldn't quite hear

24 you on that.

Page 124

1 MS. NAGLE: Object to

2 the form.

3 THE WITNESS: You know,

4 we would have tried to get more

5 information, and again, sometimes,

6 we're shared a lot of details and

7 sometimes, the suppliers provide

8 more general types of information.

9 So I don't know if we were aware at

10 that time what the specific issue

11 was.

12 BY MS. PENDLEY:

13 Q. Okay. Would you say it's

14 Torrent's routine or procedure to reach out

15 when they hear about a DMF deficiency or

16 does it just depend on the situation?

17 A. I think, typically, it would be

18 normally standard to reach out and try and

19 find out more information.

20 MS. PENDLEY: Okay.

21 Okay. We have been going about

22 another hour, how about we take

23 another quick break. Does that

24 work?

Page 125

1 THE WITNESS: Sure.

2 MS. PENDLEY: All right.

3 Let's do ten minutes.

4 THE VIDEOGRAPHER: Okay,

5 11:22. We are off the video

6 record.

7 - - - -

8 (A recess was taken at this time.)

9 - - - -

10 THE VIDEOGRAPHER: It's

11 11:46, we are on the video record.

12 BY MS. PENDLEY:

13 Q. Okay. Ms. Chitty, we were

14 telling me a little bit about the testing

15 that Torrent does before it puts a drug on

16 the market. Do you remember that?

17 A. Not really, to tell you the

18 truth, but we can jump back into a specific

19 question, I guess.

20 Q. Okay. We'll real recap some of

21 it. So you mentioned that Torrent has a

22 responsibility to test the finished dose

23 product before it goes on the market,

24 right?

Page 126

1 A. Correct.
2 Q. Okay. We can agree that it's
3 extremely important that the drugs that
4 Torrent sells are safe, right?
5 MS. NAGLE: Objection to
6 form.
7 THE WITNESS: It's
8 important that they meet the
9 standards that are in place at the
10 time, yes, which translates into
11 safety.
12 BY MS. PENDLEY:
13 Q. Okay. And the health of
14 Torrent's customer is of utmost importance
15 to Torrent, right?
16 MS. NAGLE: Objection to
17 form.
18 THE WITNESS: Correct.
19 BY MS. PENDLEY:
20 Q. Because health and safety are
21 so important to Torrent, if there's any
22 question about whether or not a drug
23 they're making is safe, Torrent should
24 investigate that, right?

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1 MS. NAGLE: Objection to
2 form.
3 THE WITNESS: As we
4 become aware of new information,
5 yes, Torrent would investigate that
6 situation.
7 BY MS. PENDLEY:
8 Q. Okay. So once Torrent is
9 informed of a contaminant in a drug, for
10 example, Torrent would have a
11 responsibility to look into that upon
12 learning that information?
13 MS. NAGLE: Objection to
14 form.
15 THE WITNESS: I don't
16 like the use of the word
17 "contaminant," but any type of
18 situation that potentially could
19 impact our products should be
20 investigated, yes.
21 BY MS. PENDLEY:
22 Q. Okay. And so that testing
23 obligation also extends to the API,
24 correct, meaning Torrent has an obligation

Page 128

1 to test the API that it's putting in its
2 products?
3 A. We are obligated to test API,
4 yes.
5 Q. Okay. And when you worked at
6 Torrent, you understood the importance of
7 testing the drug, correct? You agree that
8 that's something that Torrent should be
9 doing?
10 MS. NAGLE: Objection to
11 form.
12 THE STENOGRAPHER: We're
13 not hearing your objections.
14 MS. NAGLE: Objection to
15 form.
16 THE WITNESS: I agree.
17 BY MS. PENDLEY:
18 Q. Okay. Let's look at LP 1063.
19 This is previously marked as Torrent
20 Exhibit 25. So these emails, the way they
21 were produced, the earliest one is actually
22 on the last page, so the bottom of the
23 first page where it starts and then it
24 carries off. So this bottom email here is

Page 129

1 sent from you. Do you see that?
2 A. Yes.
3 Q. Okay. And then it is sent to
4 Sushil Jaiswal, and he works at Torrent
5 India, right?
6 A. Correct.
7 Q. This email is from August 16,
8 2018. Do you know what his position would
9 have been at this time?
10 A. I don't recall what his
11 position was at that time.
12 Q. He works for quality though,
13 doesn't he?
14 A. I, honestly, I don't remember
15 exactly what his function was at that time.
16 Q. Okay. So August 16, 2018,
17 that's around the time that you guys are
18 learning that your drug is contaminated.
19 So let's look at the body of the email.
20 You say "FDA has requested a meeting
21 tomorrow afternoon regarding taking market
22 action for valsartan products found to
23 contain NDMA." Do you see that?
24 A. Yes.

Page 130

1 Q. "Via the FDA sample analysis.
2 They've given me no more information so I'm
3 not sure if they've tested API batches or
4 finished goods." So you are clearly
5 talking about the levels of NDMA in
6 Torrent's product; is that fair?
7 A. Yes.
8 Q. Go to the next page, you say
9 "We really need a method to evaluate these
10 products ourselves," right?
11 A. Correct.
12 Q. And so what you told me earlier
13 is that testing that happens is happening
14 at Torrent India, right?
15 A. Correct.
16 Q. And so you are telling Torrent
17 India, "We really need a method to evaluate
18 these products ourselves." So you
19 understood how important it was for Torrent
20 to test its own product, right?
21 MS. NAGLE: Objection to
22 form.
23 THE WITNESS: Correct.
24 And it's not a matter of whether we

Page 131

1 were testing, the issue was having
2 a method that was good enough to
3 pick up the very small levels of
4 these impurities.
5 BY MS. PENDLEY:
6 Q. Right. So you didn't want to
7 rely on, you know, the API manufacturer,
8 you didn't want to rely on the FDA, you
9 wanted to figure this problem out for
10 yourself, right?
11 MS. NAGLE: Objection to
12 form.
13 THE WITNESS: We either
14 needed to know the FDA method or we
15 needed our own method to try and be
16 able to test at those very small
17 levels.
18 BY MS. PENDLEY:
19 Q. Okay. So what I'm trying to
20 say here is you seem to be the one that's
21 being proactive about this issue. So India
22 is the one that's doing the testing,
23 they're not coming to you saying, hey, we
24 need a method, you're having to go to India

Page 132

1 saying we need a method to test those
2 products; is that fair? You know, you're
3 the one trying to make sure that Torrent
4 figures this stuff out.
5 MS. NAGLE: Objection to
6 form.
7 THE WITNESS: From a
8 timing standpoint, this is just a
9 bit out of context for me, because
10 in this email, yes, I was telling
11 them, you know, that I thought we
12 really need a method, but there's a
13 lot of other things going on in the
14 background. You know, there's
15 communications with FDA. There's
16 communications with the API
17 supplier. And so I don't
18 necessarily think this is me for
19 the first time saying within
20 Torrent, we've got to get a method
21 for this.
22 BY MS. PENDLEY:
23 Q. Of course.
24 A. So it's just a bit out of

Page 133

1 context for me, but yes, I am aware that
2 the method and our ability to test is very
3 important.
4 Q. Okay. And so you at Torrent
5 U.S. were trying to get a test method for
6 NDMA from Torrent India, right?
7 A. I don't know if I was trying to
8 get one, but I was trying to make sure that
9 we were working towards adapting that
10 method that we normally would have used to
11 make sure that it could detect again these
12 very small levels of impurities.
13 Q. Okay. So let's look at LP
14 1394. This will be marked as Torrent
15 Exhibit 83.
16 - - - - -
17 (Email String Bates
18 TORRENT-MDL2875-00010187 to 187 marked
19 Torrent Exhibit 83 for
20 identification.)
21 - - - - -
22 BY MS. PENDLEY:
23 Q. Same idea for this email, the
24 first one is actually at the back. We're

<p style="text-align: right;">Page 134</p> <p>1 jumping around timewise a little bit, but 2 this is from 2014. You see this first 3 email is from Brijesh Patel. And he works 4 at Torrent India, right? 5 A. Correct. 6 Q. Okay. And you're on this email 7 as well as Sue Perry. She's at Torrent 8 U.S. too, right? 9 A. Yes. 10 Q. Okay. So here he's saying 11 attached is the CMC amendment for AVH, 12 that's valsartan, amlodipine, 13 hydrochlorothiazide, right? 14 A. Yes. 15 Q. "For Valsartan USP synthesized 16 by alternate manufacturing process with 17 minor change." We're going to talk about 18 the change in depth a little more in a 19 little bit. But I want you to look at 20 Sue's response with you, which part of it 21 is on page 2, part of it is on page 1. So 22 basically she's telling Brijesh that she 23 has some concerns about this process 24 change. Okay. So she says "I have some</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. And so basically Sue Perry is 2 coming to India saying we've got concerns, 3 you know, has this stuff been tested and 4 Torrent India responds with, yes, the 5 vendor has tested this, meaning ZHP has 6 tested this? 7 A. That's what it says, yes. 8 Q. It doesn't say that Torrent has 9 tested it, right? 10 A. At least on the excerpt here, 11 no, it doesn't. 12 Q. Okay. And in this excerpt, it 13 doesn't say, you know, Torrent has tested 14 and verified ZHP's results, right, not at 15 this point? 16 A. No, it does not say that here, 17 correct. 18 Q. Okay. So is it fair to say 19 that at this point, whatever results they 20 are talking about, Torrent India would have 21 to be relying on information from ZHP? 22 A. It appears that the Attachment 23 1 that's referenced here is ZHP's data. 24 Q. Okay. So the next bullet says</p>
<p style="text-align: right;">Page 135</p> <p>1 concerns with this amendment. Of course I 2 haven't seen their full DMF but; they," 3 which would be ZHP, "have used different 4 solvents, but I see nothing that indicates 5 they tested for the DMF and MTBE and they 6 were not found." Do you see that? 7 A. Yes. 8 Q. So this is a Torrent U.S. 9 employee reaching out to Torrent India 10 saying I have some concerns with ZHP's DMF 11 amendment, right? 12 A. Correct, sir. 13 Q. So she's saying, you know, she 14 wants to be sure that they have actually 15 tested to ensure certain things are not 16 found in the API; is that right? 17 A. Correct. 18 Q. Okay. And that response that's 19 hyphened under the highlighted section, 20 that's going to be Brijesh's response that 21 he puts in the email, he says "Vendor has 22 tested." The vendor would be ZHP, right? 23 A. I believe, yeah, that's the API 24 supplier in this situation.</p>	<p style="text-align: right;">Page 137</p> <p>1 "Our writeup states that the route of 2 synthesis and intermediate remain same and 3 there is not change in qualitative and 4 quantitative impurity profile." And she 5 goes on to say "Please verify that the DMF 6 manufacturer has evaluated the impurity." 7 Again, the DMF manufacturer is ZHP, right? 8 A. Correct. 9 Q. Okay. And then she goes on to 10 say you know, "and no new impurities are 11 possible with the new solvents and 12 catalysts." 13 So we see the response from 14 Torrent India again, it says "Yes, DMF 15 holder has already provided confirmation 16 for the same." So he's saying, yes, ZHP 17 has provided us with this information, 18 right? 19 A. That is what that says, yes. 20 Q. Again, it's not saying Torrent 21 has tested or Torrent has confirmed at this 22 point? 23 A. In this message, it does not 24 say that.</p>

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1 Q. And in the last one on page 2,
2 Sue asks "Have we Torrent done testing of a
3 batch of API using the new manufacturing
4 process to verify the results?"
5 And the response is, hang on,
6 it's on the top of page 2. So the response
7 is, you know, we have planned to verify the
8 testing, however, it has not been received
9 yet.
10 So at this point, Torrent U.S.
11 is, once again, asking Torrent India, can
12 we test to be sure and Torrent India is
13 saying, you know, we're planning to but we
14 haven't yet, right?
15 A. That is what this says, yes.
16 Q. Okay. And you're copied on all
17 these emails, right?
18 A. Yes, it appears I am copied on
19 that.
20 Q. Okay. And so we can see from
21 this generally that Torrent U.S. is asking
22 Torrent India to either confirm information
23 for them or test the product themselves,
24 right?

Page 139

1 A. In this email, those are
2 topics, yes.
3 Q. And like you told here earlier,
4 Torrent U.S. doesn't have the ability to
5 test the drug themselves, right?
6 A. Correct.
7 Q. So they are relying on Torrent
8 India to do it for them?
9 A. Correct.
10 Q. And they have to, right, that's
11 the way Torrent is set up?
12 A. I wouldn't say they have to,
13 had we had a lab in the U.S., we could have
14 tested, but that was not the way the
15 company was structured from a
16 responsibility standpoint at this time.
17 Q. Sure. So let me rephrase.
18 There's nothing you could do in Torrent
19 U.S. to fix that problem, it's the way
20 Torrent India structured the company?
21 A. I guess I'm not sure what
22 problem you're referring to. I mean, there
23 were certain activities and certain
24 responsibilities that were divided amongst

Page 140

1 groups. That's not a problem.
2 Q. Okay. So there's nothing you
3 could do in Torrent U.S. to test this drug,
4 right, you have to rely on Torrent India to
5 do that?
6 A. At this time currently, we had
7 no way to test ourselves.
8 Q. Okay. Let's shift gears and
9 talk about India testing in particular. So
10 despite Torrent India's obligation to test
11 the drug, at the time of the recall,
12 Torrent India still did not know how to
13 test for NDMA, right?
14 A. At the time of the recall, you
15 said Torrent India -- I'm sorry, could you
16 just repeat part of that?
17 Q. Yeah. Despite Torrent India's
18 obligations to test their product, at the
19 time of the recall, Torrent India still did
20 not know how to test for NDMA?
21 MS. NAGLE: Object to
22 form.
23 THE WITNESS: That was
24 an evolving situation.

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1 Essentially, when these initial
2 kind of conversations and data
3 started, nobody had the ability to
4 test for this impurity, you know,
5 FDA included. So the timeline of
6 this matters, so, yes, there was a
7 point where we were still working
8 on method of development along with
9 everybody else who was involved to
10 try and be able to measure for
11 those, again, what are really very
12 small quantities of impurities.
13 BY MS. PENDLEY:
14 Q. So let me clarify my question.
15 In July when valsartan was initially
16 recalled, Torrent did not have a test for
17 NDMA yet, right?
18 MS. NAGLE: Object to
19 form.
20 THE WITNESS: I have to
21 see some specifics on timeline. I
22 don't remember off the top of my
23 head when valsartan was initially
24 recalled.

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1 BY MS. PENDLEY:
2 Q. Okay.
3 A. And kind of the sequence of all
4 of these events from three years ago, I'm
5 sorry.
6 Q. All right. Let's look at LP
7 682. This was previously marked as Torrent
8 Exhibit 12. So down at the bottom of the
9 page, we see an email on August 11, 2018,
10 from you. And you're emailing, among other
11 people, Sushil Jaiswal, I believe. All
12 right. Let's see. If we can go to the
13 second page. Okay. Right there it says
14 "Hi Sushil," we can go down to what you say
15 to him, that last sentence. It says "Also,
16 have we been able to develop or transfer a
17 method to test for NDMA?" Do you see that?
18 A. Yes.
19 Q. So, once again, you at Torrent
20 U.S. are having to reach out to Torrent
21 India to figure out if you guys know how to
22 test for NDMA, right?
23 MS. NAGLE: Objection to
24 form.

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1 THE WITNESS: I'm asking
2 the question --
3 MS. PENDLEY: Right.
4 THE WITNESS: -- just to
5 try and make sure that I'm
6 informed, because at this point,
7 I'm not aware that we have a method
8 that can detect the NDMA at the
9 levels that they were expecting.
10 BY MS. PENDLEY:
11 Q. Right. And because, once
12 again, it's not Torrent U.S.'s job to test
13 the drug, they can't, right?
14 A. Correct.
15 Q. So you're having to go to
16 Torrent India whose job it is to test the
17 drug, right?
18 A. Correct.
19 Q. Okay. This is August 11. We
20 can see from this email that you are one of
21 the people that is actively encouraging
22 Torrent India to come up with a test for
23 NDMA, correct?
24 A. Correct.

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1 Q. All right. Let's look at LP
2 1039. This was previously marked as
3 Torrent Exhibit 13. Same thing, the last
4 one is at the back, so on the third page,
5 if we go to the bottom, we can see that you
6 send an email and we'll look at the fourth
7 page to see what you sent.
8 So, once again, this is from
9 you on August 17, 2018. Do you see that?
10 A. Yes.
11 Q. So this is a week after that
12 email we just looked at, right?
13 A. Correct.
14 Q. And the subject line is
15 "valsartan recall discussion needed."
16 Right?
17 A. Yes.
18 Q. Right. If we go down to page 4
19 and look at the body of your email, so you
20 can see under that underlined section, the
21 "FDA has confirmed that they tested the
22 finished goods using their own developed
23 method, GC-MS," is that gas chromatography?
24 A. Gas chromatography/mass spec,

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1 yes.
2 Q. Okay. It says "They have
3 agreed to share the method details but I
4 have not received anything of as now."
5 So as August 18, Torrent U.S.
6 at least had not received the testing
7 method from the FDA, right?
8 A. As of whatever the date of this
9 email was, I'm sorry, I just don't remember
10 if it was the 18th.
11 Q. Okay.
12 A. Something close to that.
13 Q. And you said right under that,
14 "I'm of the opinion that we need to recall
15 these five batches." Do you see that?
16 A. Yes.
17 Q. So you were making the
18 recommendation to Torrent India that you
19 guys need to recall some of your product,
20 right?
21 A. That is my opinion.
22 Q. Okay. Did you have to get
23 approval from Torrent India to do that?
24 A. Final recall decisions are made

<p>Page 146</p> <p>1 within quality assurance, so I can 2 contribute my opinion, but the final 3 decision comes from quality assurance. 4 Q. Okay. So you tell quality 5 assurance in India I think we should recall 6 these batches due to them being 7 contaminated with a nitrosamine, right? 8 A. Based on the information from 9 FDA saying they had confirmed presence of 10 that impurity, that was my opinion that 11 those five batches should be recalled. 12 Q. Okay. And like you told me 13 earlier, you had not received the actual 14 testing method from the FDA, right, so you 15 guys hadn't been able to confirm those 16 results yet; is that true? 17 A. Correct. 18 Q. Okay. But still even without 19 having been able to confirm it yourself, 20 you wanted to go ahead and recall this 21 stuff, right? 22 A. For the batches where there was 23 data that suggested the presence of the 24 impurities, yes.</p> <p>Page 147</p> <p>1 Q. Because you know that even a 2 suggestion of the presence of NDMA should 3 be taken very seriously, right? 4 A. The suggestion of the presence 5 is not enough to recall, but receiving firm 6 confirmation from FDA for these five 7 batches specifically, I felt was 8 sufficient, sufficient data to consider 9 that recall. 10 Q. Okay. So based on the 11 information that the FDA gave you, you 12 wanted to recall those batches and you made 13 the suggestion to Torrent India, right? 14 A. Correct. 15 Q. Okay. Further up in the email 16 if we could go to page 2, looking kind of 17 in the middle of the page, the email from 18 Samir. It says Samir/Corporate/Torrent 19 Limited, who is that? 20 A. He is the CEO of the 21 India-based parent company for Torrent. 22 Q. Okay. And at this point, they 23 have taken you off the email chain. Do you 24 see that?</p>	<p>Page 148</p> <p>1 A. Correct. 2 Q. So prior to today, had you ever 3 seen this email? 4 A. I don't recall specifically if 5 I've seen this before. 6 Q. Okay. On August 18, 2018, and 7 he's emailing from people including Jaiswal 8 again who is in Torrent India and he says 9 "since 26.6, what action did we take to 10 conclude if C batches had any issues or 11 not?" He's referencing valsartan, right? 12 A. It is in this trail regarding 13 valsartan, so I assume so. 14 Q. Okay. He says "Why could we 15 not find it on our own that C batches also 16 had issues rather than the FDA conveying it 17 to us?" Right? 18 A. That is what he has written. 19 Q. So in this email, like I said, 20 you're not even on it. He's asking India 21 why could we not find this out, right? 22 A. That is the question, yes. 23 Q. Because like you've told me, 24 it's India's responsibility to test this</p> <p>Page 149</p> <p>1 drug? 2 A. Correct. 3 Q. Okay. Then he goes on to say 4 on page 1, Samir again responding to the 5 same group of quality people, "How have we 6 concluded that 15 batches need to be 7 recalled and not 100?" So on August 18, 8 2018, he's asking his quality department 9 how have we concluded that the appropriate 10 number of batches have been recalled, 11 right? 12 A. Yes, that seems to be his 13 question. 14 Q. Okay. And at this point, as 15 far as you're aware, did Torrent India have 16 a method to test for NDMA? 17 A. On the 18th, I don't believe we 18 had received any information from FDA nor 19 did we have our own in-house method yet. 20 Q. Okay. So since Torrent didn't 21 yet know how to test for NDMA, can we agree 22 that it could have hired an independent lab 23 to do that for them? 24 A. Torrent could have hired a lab,</p>
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1 however, the time to develop a method, it
2 takes time, so that lab would have been
3 starting from scratch, because there was
4 not kind of out in the public domain, the
5 method of how to appropriately test for
6 these impurities, which is why we were
7 trying to get information from FDA, because
8 there's -- it's just not public knowledge,
9 the lab could go replicate and test these
10 products tomorrow and have an answer.
11 Q. Okay. So you realized that
12 another lab called Novartis was able to
13 find a lab that did mass spectrometry and
14 discovered NDMA in valsartan, right?
15 MS. NAGLE: Objection.
16 Form and foundation.
17 THE WITNESS: I'm not
18 aware of -- I don't remember who
19 first noticed this impurity. I
20 know it was not the API supplier
21 who originally initiated this
22 conversation.
23 BY MS. PENDLEY:
24 Q. Okay. Do you know that it's

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1 because one manufacturer actually hired an
2 independent lab and that's who found NDMA?
3 MS. NAGLE: Objection to
4 form.
5 THE WITNESS: No, I was
6 not aware they hired an independent
7 lab.
8 BY MS. PENDLEY:
9 Q. Okay. Torrent has actually
10 used independent labs in the past for other
11 testing assignments, right?
12 MS. NAGLE: Objection to
13 form and foundation.
14 THE WITNESS: Yes. In
15 certain circumstances where we felt
16 we couldn't perform the test
17 ourselves in-house for one reason
18 or another.
19 BY MS. PENDLEY:
20 Q. Right. And some of these
21 independent labs were actually included on
22 ANDAs that you submitted while you worked
23 for Torrent, right?
24 A. Correct.

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1 Q. All right. You actually used
2 labs called Sipra and Choksi at various
3 times, right?
4 A. Yeah, I believe those are the
5 names of some of the labs we had used.
6 Q. We can agree you never actually
7 used those labs to test valsartan API
8 specifically?
9 A. Brittney, I didn't hear that
10 objection, I'm sorry.
11 MS. NAGLE: Objection,
12 foundation.
13 THE WITNESS: I don't
14 recall if these labs were
15 specifically used for valsartan.
16 They would have been referenced in
17 the ANDA if they had.
18 BY MS. PENDLEY:
19 Q. Okay. And the ANDA has to
20 include all manufacturers and independent
21 testing facilities that were used, right?
22 A. Correct.
23 Q. So if a lab is not listed on
24 the ANDA, it was not being used for

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1 testing?
2 A. If it is being used for
3 commercial release decisions and compliance
4 decisions, it's listed. We may have labs
5 that were supporting research, for
6 instance, that may not be listed in the
7 ANDA, because those are research types of
8 activities that are going on as opposed to
9 controlling finished goods and the
10 materials that go into those finished
11 goods. Those are the companies and labs
12 that have to be listed in the ANDA.
13 Q. So if the lab was testing API,
14 it would be listed in the ANDA, right?
15 A. If it was used for commercial
16 testing of API, yes.
17 Q. Okay. Let's look at LP 1187.
18 This was marked as Torrent Exhibit 14. So
19 we can see here this is at least part of an
20 ANDA submission, right?
21 A. Yes, that looks like an ANDA
22 binder.
23 Q. All right. If you go to the
24 next page, you see the date of submission

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1 up there near the top right is
2 September 11, 2012?
3 A. Yes.
4 Q. And then your name is under
5 that, right?
6 A. Correct.
7 Q. Do you actually put these ANDAs
8 together or does someone put them together
9 and you approve them?
10 A. At various times, it has been a
11 combination. I used to have more of an
12 active hand in assembling probably earlier
13 in my time with Torrent than I would have
14 in 2012.
15 Q. Okay. So it says under product
16 description, it says for amlodipine,
17 valsartan, and hydrochlorothiazide. If we
18 could go to page 3, we can see towards the
19 end of this paragraph, it says basically
20 this is being used to add the use of Choksi
21 Labs as an outside testing lab for the
22 required routine testing of raw materials.
23 Do you see that?
24 A. I'm sorry, I'm just moving my

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1 window so I can read that whole thing.
2 Yes.
3 Q. Okay. So this lines up with
4 what you told me earlier, that when you add
5 extra labs, you have to put them in the
6 ANDA submission. So let's look at page 5
7 and so here it lists Sipra, which is the
8 lab you guys are going to stop using,
9 right?
10 A. Correct.
11 Q. And it lists everything that
12 was being tested under name of material, it
13 lists what's being tested and under tests
14 conducted it lists how it's being
15 conducted, right, or what it's being tested
16 for?
17 A. Correct.
18 Q. Okay. So if we go to the next
19 page, we can see what Choksi is going to be
20 testing and then at the top there, it says
21 "hydrochlorothiazide USP," correct?
22 A. Yes.
23 Q. Okay. So that is the API for
24 hydrochlorothiazide; is that fair?

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1 A. Yes.
2 Q. And then the rest of this stuff
3 that's listed are things like filler and
4 colorance and lubricants and things like
5 that, right?
6 A. They're essentially inactive
7 ingredients, yes.
8 Q. Okay. So we don't see
9 valsartan USP or valsartan API on this
10 list?
11 A. Correct.
12 Q. So it's safe to say that Choksi
13 Labs at this point would be not have been
14 testing valsartan API?
15 A. At this time point, no.
16 Q. Okay. Let's look at LP 1127.
17 This will be Torrent Exhibit 84.
18 -----
19 (ANDA Application Bates
20 TORRENT-MDL2875-00003433 marked
21 Torrent Exhibit 84 for
22 identification.)
23 -----
24

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1 BY MS. PENDLEY:
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 ANDA, nobody is doing testing for valsartan
 2 API, right?
 3 A. Correct.
 4 Q. Okay. LP 1130 is previously
 5 marked as Torrent Exhibit 15. Up at the
 6 top, the date of submission is February 5,
 7 2016. We can see that this is also for
 8 valsartan USP for that solo valsartan,
 9 right?
 10 A. Correct.
 11 Q. And we go to page 4. This is
 12 where they start listing the other
 13 facilities that they're using, they have
 14 ZHP at the top and on the bottom we have
 15 Sipra, one of those labs we talked about
 16 earlier. And you see in the bottom it's
 17 the last box on the page it says
 18 "Manufacturing Steps and/or type of
 19 Testing." See where it says the "testing
 20 of raw materials specifically," and then it
 21 lists a bunch of stuff. Do you see that?
 22 A. Yes.
 23 Q. Okay. So in that section what
 24 we don't see is valsartan USP, correct?

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1 A. Correct.
 2 Q. We don't see anything that's
 3 valsartan API, right?
 4 A. Correct.
 5 Q. We see that same list of the
 6 inactive ingredients is what you referred
 7 to them as, I believe, right?
 8 A. Yes, I'm not sure if it's the
 9 same, but those are all inactive ingredient
 10 tests.
 11 Q. Okay. We'll go to page 5. We
 12 see Choksi up at the top, another lab from
 13 before, and if we go down to manufacturing
 14 steps and/or type of testing, once again,
 15 it says "testing of raw materials
 16 specifically," and lists a bunch of
 17 inactive ingredients, right?
 18 A. Correctly.
 19 Q. So no valsartan API?
 20 A. Correct.
 21 Q. So at this point at least in
 22 2016, Torrent was not using an independent
 23 lab to test its valsartan API; is that
 24 fair?

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1 A. Yes, that's correct.
 2 Q. Okay. If we could look at LP
 3 1078. This was previously marked as
 4 Torrent Exhibit 16. From the top here, do
 5 you see the date, August 27, 2018, in the
 6 upper right?
 7 A. Yes.
 8 Q. And let's go to the next page,
 9 page 2. You're not on this email so, I'll
 10 walk through it a little bit slower.
 11 Basically the subject line is notification,
 12 Valsartan - no genotoxic impurity potential
 13 - Hauhai." Do you see that?
 14 A. Yes.
 15 Q. So it goes on to say "Please
 16 find batches test results, as well as list
 17 of batches supplied to Torrent with old
 18 process from 2015." Now, 2015 was three
 19 years before the recall, right?
 20 A. Yes.
 21 Q. And here one chart says "API
 22 stocks available" and lists a bunch of API
 23 batch numbers as well as parts per million.
 24 Do you see that in the first chart?

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1 A. Yes.
 2 Q. And then the bottom chart says
 3 "lot number from 2015" and also provides
 4 API batch numbers, right?
 5 A. Correct.
 6 Q. So we're going to match a
 7 couple of these up, looking at the lot
 8 numbers from 2015, six rows up from the
 9 bottom, we see the batch number C5069-15
 10 and then it ends in 049M. And then if we
 11 look at the chart on the top, we also that
 12 same batch number again, fourth row down.
 13 Are you with me so far?
 14 A. Yes.
 15 Q. So we can see that that batch
 16 has 56.5 parts per million, right?
 17 A. According to this, yes.
 18 Q. Okay. And that limit of .03,
 19 so 56.5 is over 100 times that FDA limit of
 20 NDMA?
 21 A. Again, I agree with my math,
 22 I'm not sure if that was the limit that was
 23 in place at the time of this email, but
 24 your math is correct.

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1 Q. All right. Let's look at
2 there's another batch in the 2015 table,
3 that ends in 050M and then we see that
4 batch again in the 2015 table. 56.2 parts
5 per million. Do you see that?
6 A. Yes.
7 Q. Also 100 times over the limit,
8 right?
9 A. Your math is correct, yes.
10 Q. Next row, the 2015 table ends
11 in 051M, that's on their twice and then we
12 see it twice in the 2015 table, listing
13 parts per million at 56.4. Do you see
14 that?
15 A. Yes.
16 Q. Also 100 times over the FDA
17 limit?
18 A. Math is correct, yes.
19 Q. Then we've got the one that
20 ends in 052M, we see on the 2015 at 51
21 parts per million, right?
22 A. Yes.
23 Q. Also 100 times over the FDA
24 limit?

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1 A. Yes.
2 Q. And the last one we see that
3 ends in 053M, we see it on the 2015 table
4 again and we see it in the contaminated
5 table at 63.1 parts per million. So what
6 this is telling us is that these lot
7 numbers in 2015 end up contaminated with
8 NDMA, right?
9 A. It is showing that, yes, these
10 lot numbers from 2015 contain NDMA.
11 Q. Okay. If it's a lot number
12 from 2015, does that mean it was
13 manufactured in 2015?
14 A. I'm not sure if that means it
15 was bought in 2015 or manufactured in 2015.
16 Q. All right. Well, if it was
17 bought in 2015, it would be manufactured in
18 at least 2015 if not earlier; is that fair?
19 A. Yes.
20 Q. Okay. So it was at least
21 manufactured by 2015?
22 A. At the latest in 2015.
23 Q. Okay. At the latest. So if a
24 lab knew how to test NDMA at 2015 and these

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1 batches were tested, they could have found
2 NDMA, right?
3 A. Brittney, I didn't hear that.
4 Sorry, is it just me that's not hearing
5 Brittney or is everybody else picking that
6 up?
7 THE VIDEOGRAPHER: No,
8 I'm still having a hard time
9 hearing her, yes.
10 MS. NAGLE: So,
11 objection to form, but actually,
12 Counsel, do you mind if we can,
13 around 12:30, if we can take a bit
14 of a lunch break, I can try to get
15 this mike thing situated or
16 resolved.
17 MS. PENDLEY: Yeah, I've
18 just got a few minutes, that's
19 fine.
20 MS. NAGLE: Okay. Yeah,
21 so apologies if it sounds like I'm
22 screaming at you. I just have a
23 mike issue.
24 MS. PENDLEY: No, you're

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1 fine.
2 MS. NAGLE: Thank you.
3 BY MS. PENDLEY:
4 Q. All right. Okay. So I'm
5 asking you again, so as you told me, these
6 batches were manufactured in at least 2015,
7 right?
8 A. Correct.
9 Q. So if there was a lab that knew
10 how to test for NDMA back then, and these
11 batches were tested for NDMA in 2015, they
12 could have found NDMA in 2015?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: I don't
16 believe that's what this email
17 says. This email is not implying
18 that the tests were done in 2015.
19 BY MS. PENDLEY:
20 Q. I know -- let me, let me
21 rephrase. So I'm not asking if it
22 happened. If a lab knew how to test for
23 NDMA in 2015, we can see that these batches
24 contained NDMA back in 2015, right?

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1 MS. NAGLE: Objection to
2 form.
3 THE WITNESS: Not
4 necessarily. Some impurities form
5 over time, so all you can conclude
6 from this data is that on the day
7 it was tested, it contained that
8 impurity.
9 BY MS. PENDLEY:
10 Q. Okay. You have no evidence to
11 support the fact that NDMA sporadically,
12 randomly appeared in these batches, right,
13 you know that's not how this contamination
14 happened?
15 MS. NAGLE: Objection to
16 form.
17 THE WITNESS: I'm not
18 specifically aware of how the
19 contamination happened, but I do
20 know that impurities can increase
21 over time. Whether it specifically
22 happens with this one, I do not
23 have the background to say
24 definitively yes or no.

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1 BY MS. PENDLEY:
2 Q. Okay. And so you don't have
3 the background to say definitively yes or
4 no whether NDMA can increase over time,
5 right?
6 MS. NAGLE: Objection to
7 form.
8 THE WITNESS: Correct.
9 BY MS. PENDLEY:
10 Q. Okay. I want to ask you about
11 one more thing and shift gears a little
12 bit. So we looked at some ANDAs that were
13 submitted for valsartan. Do you remember
14 the year that Torrent initially submitted
15 valsartan's ANDA for the first time?
16 A. No.
17 Q. It would be prior to 2012,
18 right?
19 A. I don't recall.
20 Q. We just looked at ANDAs with
21 2012 on them, right?
22 A. Show me a document. I'm sure
23 you have something that shows when it was
24 submitted. I'm sorry, I just can't recall

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1 random dates from three years ago, so.
2 Q. I did show you a document about
3 five minutes ago when we were looking at
4 the independent labs and it had 2012 on it.
5 Do you remember that?
6 A. Can you show it again? I
7 remember seeing something from 2012, I just
8 don't remember which product it was. We
9 have been talking about a couple of
10 different products.
11 Q. To clarify, we're only talking
12 about valsartan today. So if you were --
13 we were looking --
14 A. To clarify, you've already
15 shown me valsartan, amlodipine,
16 hydrochlorothiazide. You've shown me
17 valsartan tablets, those are different
18 products. So I just want to be accurate,
19 that's all. We sell a lot of things.
20 Q. Okay. All variations of
21 valsartan, the question I'm asking is, you
22 submit an initial ANDA and then anything
23 after that initial ANDA, is that considered
24 an amendment or is it a separate ANDA?

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1 A. If it is for the same drug
2 product, it is the same ANDA and it's an
3 amendment. If it's for a different drug
4 product, it's a separate ANDA.
5 Q. Okay. Torrent at some point
6 submitted four different ANDAs. They
7 submitted one for valsartan solo product,
8 right?
9 A. Yes.
10 Q. And they submitted for
11 valsartan and amlodipine, right?
12 A. Yes.
13 Q. And they decided one for
14 valsartan and
15 amlodipine/hydrochlorothiazide right?
16 A. Yes.
17 Q. And they submitted one for
18 valsartan/hydrochlorothiazide, right?
19 A. Yes.
20 Q. So anything after that initial
21 ANDA for each of those variations would
22 need an amendment, right?
23 A. Correct.
24 Q. So on Torrent's ANDA submission

<p style="text-align: right;">Page 170</p> <p>1 for each of those four drugs, Torrent 2 relied on ZHP's DMF, right? 3 A. I don't remember if we used ZHP 4 for all four of those products or not. 5 Q. Okay. That DMF number was 6 23491, right? 7 A. Again, I'm not remembering off 8 the top of my head, but I think that sounds 9 correct. 10 Q. Do you remember that DMF 23491 11 initially used what was referred to as a 12 TEA manufacturing process for manufacturing 13 valsartan API? 14 MS. NAGLE: Objection to 15 form. 16 THE WITNESS: I know 17 there was an old process and a 18 revised process. 19 BY MS. PENDLEY: 20 Q. If we could pull up LP 1216. 21 Let's mark this Torrent Exhibit 82. So 22 this is what we were looking at earlier 23 today, if you remember, it's in the middle 24 of the page. It's from Torrent India to</p>	<p style="text-align: right;">Page 172</p> <p>1 old process and a revised process. Do you 2 remember which manufacturing process was 3 associated with old or revised? 4 A. I'm sorry, I don't understand 5 the question. Could you -- 6 Q. Do you know -- hang on, I'll 7 show you a document. Let's look at LP 8 1219. This will be Torrent Exhibit 85. 9 And we will go to page 2. So this says "As 10 discussed, this is regarding valsartan 11 series products - Huahai API - change in 12 manufacturing process. 13 "We have filed an amendment for 14 the proposed change, which is (API 15 manufacturing process change which is the 16 major change as per the guidance) for all 17 three products as mentioned below and 18 decided to use this modified API after 19 getting approval. Meanwhile, we decided to 20 go with old process API for launch of the 21 product." Have you seen this email before? 22 A. I don't recall it specifically. 23 ----- 24 (Email String Bates)</p>
<p style="text-align: right;">Page 171</p> <p>1 you, it says "Please note that DMF holder 2 ZHP has filed an amendment to DMF 23491 for 3 valsartan USP." So that happened in 4 December 2013, right? 5 A. According to this, yes. 6 Q. And underneath it says "For the 7 same, we would like to filed an amendment 8 to our submitted ANDA for valsartan 9 tablets, amlodipine/valsartan tablets, and 10 amlodipine/valsartan/hydrochlorothiazide 11 tablets, right? 12 A. Yes. 13 Q. So if you all are filing an 14 amendment in 2013, the actual ANDA would be 15 submitted before that, right? 16 A. Correct. 17 Q. Okay. And so what we don't see 18 in this email is the 19 valsartan/hydrochlorothiazide, we only see 20 three types of valsartan here, right? 21 A. Yes. 22 Q. Do you know why that is? 23 A. No. 24 Q. Now, you mentioned to me the</p>	<p style="text-align: right;">Page 173</p> <p>1 TORRENT-MDL2875-00085415 to 85416 2 marked Torrent Exhibit 85 for 3 identification.) 4 ----- 5 BY MS. PENDLEY: 6 Q. Okay. Does any of this new 7 process/old process stuff sound familiar to 8 you? 9 A. Yes. 10 Q. Okay. So they're saying they 11 applied, they submitted the ANDA with old 12 process API, right? 13 A. Originally, yes. 14 Q. Okay. And then they filed an 15 amendment for the new process API, right? 16 A. Correct. 17 Q. Okay. And then we see here, 18 again, it's only the three types of 19 valsartan not the 20 valsartan/hydrochlorothiazide. So for 21 valsartan tablets, it says the amendment 22 was filed in April 2014 and under the 23 remarks column it says "The proposed change 24 was not accepted by the FDA." So that</p>

<p style="text-align: right;">Page 174</p> <p>1 means the proposed change to use the new 2 process was not accepted by the FDA. Do 3 you see that? 4 A. Yes. 5 Q. Do you have any idea why that 6 was? 7 A. It potentially was around 8 timing of approval of the original 9 application. FDA doesn't like it if you 10 submit significant information too close to 11 an expected approval or action date, which 12 is kind of what this sounds like. They 13 like many months' worth of time to review 14 what's referred to here I think as a major 15 type of change. 16 Q. Okay. So you mentioned they 17 don't like information submitted close to a 18 major approval date. So if that were the 19 reason this was not accepted, would that 20 mean that valsartan's ANDA had been 21 approved already or that it had not been 22 approved yet? 23 A. I am guessing by the time, and 24 we can obviously check this, I don't</p>	<p style="text-align: right;">Page 176</p> <p>1 Q. And AVH, which is the 2 amlodipine/valsartan/hydrochlorothiazide, 3 right? 4 A. Yes. 5 Q. "Tablets and decided to file 6 PAS with one batch data after getting 7 approval." So they're saying we expected 8 to get the same remark from the FDA, but 9 just haven't yet; is that right? 10 A. That's the way I read that, 11 yes. 12 Q. Do you know of them ever 13 getting this question from the FDA about 14 these two batches? 15 A. I'm not sure. 16 MS. NAGLE: Objection to 17 form. 18 THE WITNESS: Sorry. 19 BY MS. PENDLEY: 20 Q. I'm just clarifying my 21 question. You're okay. 22 A. It would be in the 23 communication files for those ANDAs if we 24 did receive comments regarding that</p>
<p style="text-align: right;">Page 175</p> <p>1 remember exactly when it was approved, but 2 I think it was approved after this date of 3 April 2014. 4 Q. Okay. So we can see that the 5 change was not approved for valsartan solo 6 tablets, but then when we see the 7 amlodipine, and we see the 8 amlodipine/valsartan/hydrochlorothiazide, 9 apparently the FDA had no comment on this 10 amendment. Do you see that? 11 A. I'm not sure. I'm just reading 12 the other part of the email here. It looks 13 to me that based on the rest of the text 14 there, we just had not heard back on those 15 two specific applications yet. Because it 16 goes on to say that we're going to do the 17 same thing we're doing for valsartan and 18 file it after getting final approval for 19 those drug products as well. 20 Q. Okay. Thank you. Look under 21 this chart, second little paragraph it says 22 "We expected the query for A," which is 23 amlodipine, right? 24 A. Yes.</p>	<p style="text-align: right;">Page 177</p> <p>1 valsartan API change. 2 Q. All right. It goes on to say 3 "But, we have received the final achieve 4 for A and AVH tablets without any query 5 from FDA for the modified. Hence we can 6 use modified manufacturing process API 7 directly." So they're saying we received 8 approval for new process from the FDA? 9 A. It says, so as I read that 10 paragraph, it seems like we did not receive 11 comments then on the amlodipine/valsartan 12 and the AVH prior to final approval of the 13 drug product. 14 Q. Okay. So does that mean they 15 can use the new process now or not? 16 A. If it was submitted as an 17 amendment and there were no questions, yes, 18 they can use it. 19 Q. Okay. So as far as you're 20 aware, did Torrent actually use this new 21 manufacturing process in any of its 22 valsartan product? 23 A. I don't recall. I know there 24 were lots of communications regarding old</p>

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1 process versus new process, so I would have
 2 to go back to the communications to say for
 3 certain.
 4 Q. I'm going to ask you about a
 5 couple of more documents, if we could do LP
 6 1234. This will be Torrent Exhibit 86.
 7 -----
 8 (Email String Bates
 9 TORRENT-MDL2875-00156990 to 156993
 10 marked Torrent Exhibit 86 for
 11 identification.)
 12 -----
 13 BY MS. PENDLEY:
 14 Q. Turn to page 3. You're not on
 15 this email. It seems to be between mostly
 16 Indian employees. And near the bottom of
 17 the page, it says "Beyond 2015, it will not
 18 be process to provide old process valsartan
 19 from ZHP." Do you see that?
 20 A. Yes.
 21 Q. Did you ever hear anything else
 22 about this as to whether or not they were
 23 able to to continue to buy old process from
 24 ZHP?

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1 A. I'm really -- I don't remember.
 2 I'm not aware whether we were still buying
 3 old process after 2015.
 4 Q. Okay. Do you know who would be
 5 aware of that?
 6 A. Likely someone within
 7 procurement.
 8 Q. Okay. So whoever was in
 9 procurement in 2015 would be the person we
 10 should ask about that?
 11 A. Probably 2015 or after, yeah.
 12 Q. Okay. Okay. Okay. Let's look
 13 at LP 193. This will be Torrent
 14 Exhibit 87.
 15 -----
 16 (Email String Bates
 17 TORRENT-MDL2875-00030454 to 90463
 18 marked Torrent Exhibit 87 for
 19 identification.)
 20 -----
 21 BY MS. PENDLEY:
 22 Q. And we'll go to page 2. Okay.
 23 So this says "Please kindly note the batch
 24 numbers for the valsartan API based on zinc

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1 chloride process. We supplied these since
 2 August 2013." Do you see that?
 3 A. No, I don't.
 4 MS. NAGLE: Yeah, I
 5 don't think that's what's on the
 6 screen.
 7 MS. PENDLEY: Let me see
 8 where we are. It's looks like the
 9 same email, just in chart form. We
 10 can do it with LP 208. This will
 11 be Torrent Exhibit 88.
 12 -----
 13 (Valsartan New Process Batch
 14 Tracking Bates
 15 TORRENT-MDL2875-00090464 marked
 16 Torrent Exhibit 88 for
 17 identification.)
 18 -----
 19 BY MS. PENDLEY:
 20 Q. So this we can see it says
 21 "Valsartan New Process Batch Tracking." Do
 22 you see that?
 23 A. Yes.
 24 Q. So this would be referencing

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1 that new or revised process you were
 2 telling me about?
 3 A. I believe so.
 4 Q. If we look at the last column
 5 here, it says "PO date." What do you think
 6 that means?
 7 A. PO stands for purchase order.
 8 Q. Okay. So all the dates in that
 9 column would be the purchase order date,
 10 right?
 11 A. I believe so, yes.
 12 Q. All right. And if we look at
 13 the market, which is the column on the far
 14 left-hand side, we see that they're all for
 15 the U.S., right?
 16 A. The top section is for the U.S.
 17 The bottom section is for Europe.
 18 Q. Okay. So the whole top section
 19 is U.S. Let's look at the lot numbers. We
 20 can see these are all batches that start
 21 with D5191, right?
 22 A. Correct.
 23 Q. All right. And then this
 24 spreadsheet is titled "New Process Batch

<p>Page 182</p> <p>1 Tracking." So I want to ask you a couple 2 of questions about whether or not this 3 stuff got used in finished product, if you 4 know. So the batch status column says 5 things like used for development. What 6 does that mean? 7 A. It means that we were using 8 that essentially for research, you know, 9 potentially for developing different types 10 of tablets that we would eventually use, 11 you know, working on stability potentially 12 and in a research and development capacity. 13 Q. Okay. What does 56 kilograms 14 used for EB, what does EB mean? 15 A. EB typically stands for exhibit 16 batch, which is the batch we use that would 17 eventually be submitted potentially in an 18 ANDA. 19 Q. All right. Why would something 20 be blocked? 21 A. Do not know. 22 Q. Why would it be under custom, 23 do you know? 24 A. Under custom means it's under</p> <p>Page 183</p> <p>1 customs clearance. 2 Q. Okay. What's involved in 3 clearing something from customs? 4 MS. NAGLE: Objection. 5 Form and foundation. 6 THE WITNESS: I don't 7 know. 8 BY MS. PENDLEY: 9 Q. All right. So do you have any 10 knowledge as to whether or not these new 11 process batches were ever used in valsartan 12 sold in the U.S.? 13 A. Not from this sheet, no. 14 Q. Do you have any knowledge not 15 from this sheet whether or not it made it 16 to the U.S.? 17 A. We would have to go back and 18 look at more documents. We were tracking 19 old process/new process batches and where 20 that was in the supply chain potentially, 21 so there should be information that covers 22 that. 23 Q. Okay. And then that batch 24 number, last thing, some of them end in M,</p>	<p>Page 184</p> <p>1 I think they all do on this sheet, but what 2 does it mean when the batch ends in the 3 letter M, do you know? 4 A. No, I don't know. 5 Q. So you don't know the 6 difference between a single M and a double 7 M and all that? 8 A. No. 9 Q. Do you know who would know 10 that? 11 A. Somebody within the plant would 12 know kind of what all of those details go 13 into the numbering and naming of batches. 14 Q. Okay. The plant in India? 15 A. Correct. 16 Q. Okay. Okay. What do you say 17 we break for lunch? 18 A. Sounds good. 19 MS. NAGLE: Thank you. 20 MS. PENDLEY: All right. 21 Let's do an hour. 22 THE VIDEOGRAPHER: 12:46 23 p.m., we are off the video record. 24 - - - -</p> <p>Page 185</p> <p>1 (A recess was taken at this time.) 2 - - - - 3 THE VIDEOGRAPHER: 1:47, 4 we are on the video record. 5 BY MS. PAPANTONIO: 6 Q. All right. Good afternoon, 7 Ms. Chitty. My name is Sara Papantonio. 8 I'm going to be doing the remaining 9 questioning here. Okay? 10 A. Sounds good. 11 Q. All right. Now, Ms. Chitty, 12 you have been in this industry for a long 13 time; isn't that right? 14 A. Yes. 15 Q. And working in the 16 pharmaceutical industry since 2000, about 17 2002? 18 A. A little before that. I was a 19 chemist and I worked in a lab before that, 20 but yeah, roughly. 21 Q. You're actually an organic 22 chemist; isn't that right? 23 A. Correct. 24 Q. And with that chemistry degree,</p>
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1 you also have over 20 years of experience
2 in regulatory affairs; is that right?
3 A. Correct.
4 Q. So you're no stranger to this
5 industry, you absolutely know how it works,
6 right?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: I am
10 familiar with the responsibilities
11 that I've had over my time in the
12 industry, yeah.
13 BY MS. PAPANTONIO:
14 Q. Right. And because of how much
15 time you spent in this industry, you
16 actually counsel other pharmaceutical
17 companies, right, on how to follow the
18 regulations?
19 A. In my current position,
20 correct.
21 Q. Right, in your current
22 position, you teach other companies how to
23 comply with the FDA standards?
24 A. Compliance is not a huge part

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1 of my current role, but we advise on other
2 types of guidelines and regulations, yes.
3 Q. Okay. And we can agree that no
4 company would ever want to have to go
5 through a recall, right?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: Ideally,
9 no.
10 BY MS. PAPANTONIO:
11 Q. And so part of your role as a
12 consultant is you actually get to advise
13 companies on how to stay within all the
14 regulations and how to avoid certain
15 recalls, right?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: My current
19 focus is more on development work
20 as opposed to commercial activities
21 currently.
22 BY MS. PAPANTONIO:
23 Q. So developing regulatory
24 departments in pharmaceutical companies?

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1 A. Developing products that are
2 under evaluation for eventual marketing in
3 the U.S.
4 Q. Okay. Well, with all that
5 experience in mind, I want to talk about
6 your time at Torrent, because you put a lot
7 of years into Torrent, didn't you, 14,
8 right?
9 A. Correct.
10 Q. And so you actually, you know,
11 you didn't start as vice president of
12 science, you had to work your way up to
13 that; isn't that correct?
14 A. Yeah, vice president of
15 regulatory and eventually strategy and
16 scientific affairs.
17 Q. Did you enjoy your time at
18 Torrent?
19 A. I did.
20 Q. We're going to talk about the
21 time in terms of the recall, because we
22 were talking earlier about the use of a
23 timeline. So I'm going to actually use a
24 timeline throughout our testimony so we can

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1 really understand the breakdown of what
2 happened while you were at Torrent. Okay?
3 A. Sure.
4 Q. From me taking notes of dates
5 as we go and we're going to start with LP
6 1385. That is going to be marked as
7 Torrent 89.
8 - - - - -
9 (Email String Bates
10 TORRENT-MDL2875-00005067 to 5068
11 marked Torrent Exhibit 89 for
12 identification.)
13 - - - - -
14 BY MS. PAPANTONIO:
15 Q. Okay. We can see this is an
16 email. And we can also see that you
17 received this email, right, under cc, Dawn
18 Chitty?
19 A. Correct.
20 Q. Do you remember this email?
21 A. Not specifically, no.
22 Q. Okay. It looks like it is sent
23 on July the 6th, 2018. Okay. And so
24 before we get into the contents of the

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1 email, I just want to talk generally.
2 Torrent supplies drugs to countries all
3 over the world, right?
4 A. Correct.
5 Q. Countries like Brazil, Spain,
6 all kinds of European countries?
7 A. Brazil --
8 MS. NAGLE: Objection.
9 Form and foundation.
10 THE WITNESS: Sorry,
11 Brazil, yes. I'm not sure about
12 which specific EU countries, but we
13 did business in EU.
14 BY MS. PAPANTONIO:
15 Q. Right. And the company you
16 work for, Torrent USA, is ultimately
17 responsible for monitoring the valsartan in
18 USA, right?
19 A. The U.S. company is not solely
20 responsible for, I guess, monitoring that
21 product. It's, as we've talked earlier,
22 kind of a partnership between the parent
23 company in India as well as us in the U.S.
24 Q. Right. But for the most part,

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1 Torrent USA is monitoring Torrent USA
2 drugs?
3 A. I don't know if I agree with
4 the word "monitoring." We are obviously
5 aware of what's going on and helping in the
6 development of products for the U.S.
7 market.
8 Q. Okay. And as part of that
9 development, if Torrent USA learned that
10 another country had found something wrong
11 with one of its products that you also sell
12 in the U.S., you would want to know that
13 information, right?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: We do like
17 to know of analogous products in
18 other markets, yes.
19 BY MS. PAPANTONIO:
20 Q. So if a country found out that
21 valsartan was potentially dangerous, that
22 information would be relevant to your job
23 in Torrent USA?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: Dangerous
3 is kind of strange in that sentence
4 the way it is worded, but as I
5 said, if we have other information
6 regarding a product that's similar
7 to what we use in the U.S., it
8 would be useful to know that.
9 BY MS. PAPANTONIO:
10 Q. Okay. And when you're dealing
11 with compliance issues in the United
12 States, you would agree it's better to be
13 proactive than it is to be reactive?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: Compliance
17 is kind of a continuous thing. You
18 need to build compliance and steps
19 into everything that you do.
20 BY MS. PAPANTONIO:
21 Q. Right, exactly. It is
22 important that you take steps to ensure
23 that the drug you're selling is a quality
24 drug?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: I would
4 agree with that statement.
5 BY MS. PAPANTONIO:
6 Q. You would want to know if
7 there's a quality issue with a drug before
8 it actually becomes a problem on the
9 market?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: The sooner
13 you know any issues, the better.
14 BY MS. PAPANTONIO:
15 Q. Okay. With that in mind, let's
16 take a look at this email. Like we said,
17 these emails start from the back, but we're
18 only going to look at the first page,
19 because the back page is not relevant.
20 Now, we can see this is an
21 email from Humana to Torrent Pharma USA.
22 Who is Chip McCorkle?
23 A. Chip is one of -- was one of
24 Torrent's salespeople in the U.S.

<p>Page 194</p> <p>1 Q. And it says "Please see the 2 attached news release regarding the Europe 3 recall of valsartan-containing products." 4 Do you recall the Europe recall of 5 valsartan-containing products? 6 A. I remember it happening. I 7 don't necessarily remember in the sequence 8 of events, but I see it here. 9 Q. And then we can see these news 10 articles say, in the link it says the 11 title, so it says "Europe recalls generic 12 heart drug made in China on cancer fears." 13 Do you see that? 14 A. Yes. 15 Q. Cancer fears, that's a red flag 16 in the pharmaceutical industry, right? 17 MS. NAGLE: Objection, 18 form. 19 THE WITNESS: I mean, 20 again, it's the title of an 21 article. You know, I hate to -- I 22 can't put too much credence in the 23 wording, I guess, of the way it's 24 worded, but.</p> <p>Page 195</p> <p>1 BY MS. PAPANTONIO: 2 Q. Right, but if you see, if you 3 see a drug that you sell, valsartan, 4 associated with the word "cancer," that 5 would be information to you, right, 6 information that you would have to have? 7 MS. NAGLE: Objection, 8 form. 9 THE WITNESS: 10 Information that I would like to 11 have, yes. 12 BY MS. PAPANTONIO: 13 Q. And it says, it recalls the 14 generic heart drug made in China. That 15 would be ZHP, right, your Chinese API 16 manufacturer? 17 MS. NAGLE: Objection. 18 Form and foundation. 19 THE WITNESS: From the 20 title of the article, I'm not sure 21 which product that's referring to. 22 BY MS. PAPANTONIO: 23 Q. Okay. And then someone is 24 responding to you. We've got, it looks</p>	<p>Page 196</p> <p>1 like Chip is responding or writing you a 2 letter. And he's asking "Is this a problem 3 for Torrent?" Now, at this point, do you 4 believe this is a problem for Torrent that 5 there's cancer in or cancer -- excuse me, 6 move to strike. 7 At this point, would it be a 8 problem that valsartan is linked to cancer 9 in Europe? 10 MS. NAGLE: Objection, 11 form. 12 THE WITNESS: You have 13 to really understand the details 14 of, again, the product and the 15 situation in Europe. We were aware 16 in this early July time frame 17 through our communications with ZHP 18 that they were investigating 19 potential issues with their route 20 of -- their new route of synthesis. 21 BY MS. PAPANTONIO: 22 Q. Okay. And he further says "A 23 quick glance our API supplier -- at our API 24 supplier looks like we do source our API</p> <p>Page 197</p> <p>1 from this company in China." So it's safe 2 to say we are talking about ZHP, right? 3 A. I believe so. There was a link 4 there from ZHP further down too, so I'm not 5 sure what, again, is referred to in the 6 news article that was referenced, but 7 there's information there from ZHP 8 specifically itself too. 9 Q. Now, as far as you know, after 10 receiving notice that Europe was recalling 11 their valsartan based on cancer fears, did 12 Torrent USA ever take any measures to test 13 the drug to see if you might have the same 14 problem? 15 MS. NAGLE: Objection, 16 form. 17 THE WITNESS: As I've 18 mentioned already, most of the 19 testing was pretty much exclusively 20 done by our team in India, so I was 21 vaguely aware we were looking into 22 the issue. I do not know of the 23 specific actions that were taken 24 from this email and this article</p>
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1 specifically.
 2 BY MS. PAPANTONIO:
 3 Q. As far as you know, did anyone
 4 from Torrent India insinuate that the drug
 5 needed to -- the U.S. product needed to be
 6 tested for this cancer-causing carcinogen?
 7 A. I think at this time in July,
 8 we were still gathering a lot of
 9 information and wanting to, you know,
 10 develop methods that might be able to help
 11 us detect these small amounts of
 12 impurities, but again, I think at this
 13 stage in the timeline, the expectation was
 14 that the new API route of synthesis product
 15 was impacted, which we believed we did not
 16 have on the market at the time.
 17 Q. Right. And if you had tested
 18 valsartan U.S. product at this time for
 19 NDMA, you would have learned that that
 20 product was in fact contaminated with NDMA?
 21 MS. NAGLE: Objection.
 22 Form and foundation.
 23 THE WITNESS: Not
 24 necessarily. We had a method in

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1 place at times -- at the time of
 2 this for testing our product for
 3 release and it was not detecting
 4 the very small amounts of NDMA.
 5 BY MS. PAPANTONIO:
 6 Q. We're going to talk about that
 7 testing in a little bit, but now I want to
 8 move to LP 1170. This has already been
 9 marked as Torrent 19. So we can see this
 10 document is dated June 20. So this is when
 11 the contamination story really starts for
 12 Torrent, right?
 13 A. This is the date that we were
 14 notified that there was a new unknown
 15 impurity in the ZHP API.
 16 Q. I want to break this down. You
 17 got this notification from your API
 18 manufacturer, ZHP, right?
 19 A. It seems, yes, that's where
 20 that came from.
 21 Q. And it says "Recently, we
 22 became aware of a previously unknown
 23 impurity." What does impurity mean?
 24 A. An impurity is something

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1 besides the active ingredient or the
 2 inactive ingredients in a drug product.
 3 Q. Right, impurity means not pure,
 4 right?
 5 MS. NAGLE: Objection to
 6 form.
 7 THE WITNESS: By its
 8 pure definition, that's a likely
 9 definition, yeah.
 10 BY MS. PAPANTONIO:
 11 Q. It means that's something is
 12 wrong with the drug?
 13 MS. NAGLE: Objection,
 14 form.
 15 THE WITNESS: No, I
 16 would not draw that conclusion.
 17 BY MS. PAPANTONIO:
 18 Q. Well, if an impurity has
 19 genotoxic potential, that means that it's a
 20 cancer-causing impurity, correct?
 21 MS. NAGLE: Objection,
 22 form.
 23 THE WITNESS: No, again,
 24 it says "may have genotoxic

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1 potential."
 2 BY MS. PAPANTONIO:
 3 Q. "May have genotoxic potential,"
 4 so that means it may cause cancer?
 5 MS. NAGLE: Objection,
 6 form.
 7 THE WITNESS: As written
 8 here, I really can't elaborate any
 9 further. As we've discussed
 10 already, I'm not a toxicologist,
 11 so.
 12 BY MS. PAPANTONIO:
 13 Q. Right, but you are an organic
 14 chemist; isn't that right?
 15 A. Correct.
 16 Q. Did you ever study genotoxicity
 17 in your master's degree?
 18 A. Twenty-five, 30 years ago, yes.
 19 Q. So you at least have a
 20 foundation for it, right?
 21 A. I have a very minimal
 22 understanding. Again, it's not my area of
 23 expertise.
 24 Q. Okay. And at a minimum, what

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<p>1 we know is that something with genotoxic 2 potential is not something that we would 3 want to ingest? 4 MS. NAGLE: Objection, 5 form. 6 THE WITNESS: If you can 7 avoid it, that would probably be 8 advisable. 9 BY MS. PAPANTONIO: 10 Q. Okay. And so what we know now, 11 we didn't know at the time, what Torrent 12 knows now is that this genotoxic impurity 13 was actually NDMA, right? 14 A. That is, I believe, what that 15 impurity turned out to be, yes. 16 Q. So on June 20, 2018, were you 17 aware that the only medical use of NDMA was 18 actually to form tumors in lab rats? 19 MS. NAGLE: Objection, 20 form. 21 THE WITNESS: No, I was 22 not aware of that. 23 BY MS. PAPANTONIO: 24 Q. Were you that NDMA is a</p>	<p>1 specific chemical based on the method we 2 had at the time. 3 Q. So based on the method that 4 Torrent had -- let me just make I'm 5 understanding this, based on the method 6 that Torrent had, you could test to see if 7 NDMA was present, but you could not test 8 the level of NDMA in the product; is that 9 right? 10 A. I can't even say that you could 11 test for its presence at this point in the 12 status of the method essentially. 13 Q. Okay. And so at this point, 14 Torrent USA is relying on information that 15 they're getting from ZHP in China, right? 16 MS. NAGLE: Objection to 17 form. 18 THE WITNESS: I don't 19 know if I can say relying on. I 20 mean, this is one piece of 21 information that we had received. 22 BY MS. PAPANTONIO: 23 Q. Okay. And we're going to walk 24 through how Torrent reacted to this. LP</p>
Page 203	Page 205
<p>1 chemical that they used to form rocket 2 fuel? 3 MS. NAGLE: Objection, 4 form. 5 THE WITNESS: No, I'm 6 not aware of that. 7 BY MS. PAPANTONIO: 8 Q. At this point, July 20, did you 9 know just how dangerous NDMA was as a 10 carcinogen? 11 MS. NAGLE: Objection, 12 form. 13 THE WITNESS: I was not 14 aware of NDMA -- now I can't say 15 the right letters, sorry, NDMA at 16 this date at all. 17 BY MS. PAPANTONIO: 18 Q. That's fine. We'll just call 19 it a carcinogen. So what's happening right 20 now is Torrent can't actually test the 21 product to determine if the carcinogen is 22 present in their valsartan, right? 23 A. You can test the product at 24 this point, but we could not detect that</p>	<p>1 1169. Do you recognize this document, 2 Ms. Chitty? 3 A. I don't know if I remember it 4 specifically, but it's addressed to me. 5 Q. We'll walk through it. We can 6 see that it's a Torrent document. It has 7 got Torrent Pharma up in the right-hand 8 corner and we see it is a letter written to 9 you, right? 10 A. To me, yes. 11 Q. And this was on July 7. And 12 this letter is from Vijay Patel. Who is 13 that? 14 A. I'm sorry, I'm just moving my 15 screen around so I can see the bottom of 16 the document. It says that he's the 17 assistant general manager from QA at our 18 parent company in India. 19 Q. Did you communicate with 20 Mr. Patel on a regular basis? 21 A. I honestly don't remember. 22 Q. Okay. But we do know that 23 Mr. Patel is from Torrent India, right? 24 A. Yes, according to his signature</p>

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1 block there.
2 Q. Okay. And so this is two
3 weeks, what we can see this is on July 7,
4 so it's two weeks after you got official
5 notice from ZHP that there is a genotoxic
6 impurity in valsartan, right?
7 A. It is approximately two weeks
8 after that initial notification, yes.
9 Q. So at this point, July 7,
10 Torrent USA has to make a decision, right?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: Torrent
14 U.S. is not the decisionmaker
15 essentially, as I've stated before.
16 BY MS. PAPANTONIO:
17 Q. Well, you've got to communicate
18 to the FDA whether or not you are going to
19 recall U.S. valsartan, right?
20 A. I'm just going to take a minute
21 and read this.
22 Q. We'll walk through it together.
23 Let's read it together. So what he's
24 telling you is starting on that first line,

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1 which we already know, "We received a
2 notification from valsartan API
3 manufacturer ZHP dated the 6th -- or 26th
4 of June regarding a genotoxic impurity
5 observed in the valsartan." Right, that's
6 the document we just saw. Do you remember
7 that?
8 A. Was that other document from
9 the 20th or the 26th? I don't think that's
10 the document this letter is referring to.
11 Q. Okay. But we do know you
12 received word from ZHP?
13 A. Correct.
14 Q. And then Mr. Patel writes that
15 "Hauhai has informed that they're using two
16 manufacturing processes." And we kind of
17 talked about that earlier today, there's an
18 old process and there's a new process,
19 right?
20 A. Correct.
21 Q. And Torrent U.S. only used that
22 old process?
23 A. Again, the timing of this, yes,
24 I believe we were only using the old

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1 process.
2 Q. So Mr. Patel in the next line
3 is telling us that genotoxic impurity
4 identified is in the new process and but we
5 can see that this is based on the
6 information that ZHP provided Torrent,
7 right?
8 MS. NAGLE: Objection,
9 form.
10 THE WITNESS: I'm not
11 sure if that's based upon the
12 June 26 letter or not. We haven't
13 seen that.
14 BY MS. PAPANTONIO:
15 Q. Well, let's look at this second
16 paragraph. It says Hauhai has informed us
17 or has informed, right, so we know that
18 Torrent is getting information from ZHP?
19 A. That they're using two
20 manufacturing processes, yes.
21 Q. And that there is no NDMA in
22 the new process, that's what we conclude in
23 this last -- let's look at this last
24 paragraph, it says "These batches were

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1 manufactured and tested according to
2 standard approved process by using the old
3 API process, hence, it does not pose any
4 adverse quality impact," right? Do you see
5 that?
6 A. Yes, that's what it says.
7 Q. So Torrent is relying on
8 information from ZHP and concludes that
9 there's no adverse quality impact to U.S.
10 valsartan?
11 A. Correct.
12 Q. Right. And so what we
13 ultimately conclude here is no market
14 action is required, right?
15 A. As of this date, yes.
16 Q. That means Torrent USA can
17 continue selling the drug?
18 A. Was that a question, I'm sorry?
19 Q. Right. Is that what that
20 means, if there's no market action, you can
21 continue to supply the drug and sell the
22 drug?
23 A. Correct.
24 Q. And so, like you said, Torrent

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1 USA is not making the decision whether or
2 not to recall, they're getting that
3 information from Torrent India, right?
4 A. Yes.
5 Q. So you're just following orders
6 at this point?
7 A. Correct.
8 Q. Okay. And at this point, on
9 July 7, if Torrent had actually developed a
10 test to detect NDMA in their valsartan,
11 Torrent would have found that the valsartan
12 was contaminated with NDMA?
13 MS. NAGLE: Objection.
14 Form and foundation.
15 THE WITNESS: I can't
16 say definitively what they would
17 have found at this point.
18 BY MS. PAPANTONIO:
19 Q. You're aware that Torrent
20 valsartan was recalled in the end?
21 A. Some of it was, yes.
22 Q. And you're aware it was
23 recalled because of the presence of NDMA?
24 A. In the affected batches, yes.

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1 Q. So if you had tested a range of
2 batches at this time, Torrent would have
3 found that NDMA was present in those
4 batches?
5 MS. NAGLE: Objection.
6 Form and foundation.
7 THE WITNESS: Again, if
8 the method was suitable to have
9 detected the NDMA, it could have
10 detected that presence at that
11 time.
12 BY MS. PAPANTONIO:
13 Q. And had you detected that
14 presence, the valsartan would have been
15 taken off the market, right?
16 MS. NAGLE: Objection.
17 Form and foundation.
18 THE WITNESS: Typically,
19 once we have new data, we would
20 reevaluate.
21 BY MS. PAPANTONIO:
22 Q. And as far as you're aware, did
23 anyone from Torrent India come to you and
24 say, we have tested the valsartan batches,

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1 they are free of NDMA?
2 A. I don't recall specifically.
3 Q. So what we can see here is that
4 Torrent India is simply relying on the
5 statements made by ZHP?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: In this
9 message, it seems that they were
10 utilizing information from ZHP.
11 BY MS. PAPANTONIO:
12 Q. And we would hope that at the
13 time, ZHP was giving accurate information,
14 right?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: I would
18 hope, yes.
19 BY MS. PAPANTONIO:
20 Q. This one was, sorry, I forgot,
21 this one is marked as Torrent 20. Okay.
22 Next we're going to look at 1093, which is
23 marked as Torrent 21. All right. Let's
24 start from the back here. Okay. Let's

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1 blow up that last email. Okay. So ZHP
2 notifies you on June 20 of the
3 contamination and this is -- or excuse me,
4 yeah, June 20 and this is July 10, correct?
5 A. That is the date of this email.
6 Q. It's about 20 days later?
7 A. Roughly, yes.
8 Q. So this is about -- this is
9 over two weeks after Torrent has learned
10 that there's a cancer-causing compound in
11 valsartan?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: Again, the
15 phrasing has been in our
16 communications from ZHP that it was
17 potentially there. The, you know,
18 message or the memo that we looked
19 at just previously confirmed that
20 our belief was it only impacted the
21 new process API, which we had not
22 utilized.
23 BY MS. PAPANTONIO:
24 Q. Right. And that's information

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1 that you're relying on from ZHP still at
2 this time?

3 MS. NAGLE: Objection,
4 form.

5 THE WITNESS: As of the
6 10th of July, I can't really speak
7 to what other testing Torrent might
8 have done.

9 BY MS. PAPANTONIO:

10 Q. But as far as you know, up to
11 this point, July 10, Torrent still has no
12 capabilities of testing for NDMA in its
13 product?

14 A. Correct.

15 Q. And so this email is to you
16 from Arun Verma. Who is that?

17 A. Arun was the chief operating
18 officer for the U.S. Torrent-based company.

19 Q. And he's telling you that we
20 need to communicate to our customers our
21 quality position on this product. Ms.
22 Chitty, I mean, working in regulatory, you
23 know how important it is to communicate
24 with customers, right?

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1 MS. NAGLE: Objection to
2 form.

3 THE WITNESS: That's not
4 really a regulatory concern for me,
5 communicating with customers. I
6 was communicating with FDA
7 primarily.

8 BY MS. PAPANTONIO:

9 Q. Well, just generally, you
10 understand the importance of communicating
11 quality issues to customers who take your
12 product, right?

13 MS. NAGLE: Objection,
14 form.

15 THE WITNESS: It's
16 important to keep our customers
17 informed if there is any concern or
18 indication that there may be a
19 quality issue, yes.

20 BY MS. PAPANTONIO:

21 Q. Absolutely. And let's talk
22 about why that's important. It's important
23 because customers take this product
24 sometimes every day, right?

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1 A. People routinely take our
2 products every day.

3 Q. Yeah, and it's used to treat
4 high blood pressure, right?

5 A. Correct.

6 Q. So it's important to know if a
7 drug that you're taking every single day
8 potentially has a carcinogen in it,
9 correct?

10 MS. NAGLE: Objection,
11 form.

12 THE WITNESS: Consumers
13 have, you know, a certain amount of
14 information that's available with
15 them and so do doctors and kind of
16 all of the other relevant people
17 who can help them make decisions
18 about what they're taking every
19 day.

20 BY MS. PAPANTONIO:

21 Q. Right. They have got to be
22 able to make an informed decision about the
23 product that they're using?

24 MS. NAGLE: Objection,

Page 217

1 form.

2 MS. PAPANTONIO: Right?

3 THE WITNESS: I would
4 agree.

5 BY MS. PAPANTONIO:

6 Q. For instance, Ms. Chitty, if
7 you were taking a drug that potentially had
8 a carcinogen in it, you would want to know?

9 MS. NAGLE: Objection,
10 form.

11 THE WITNESS: I would
12 want to know that information so
13 that I could talk with my doctor
14 essentially.

15 BY MS. PAPANTONIO:

16 Q. Okay. And let's go a few
17 emails up on this to the -- this is the
18 second page, to the email dated July 11.
19 Again, we can see that you're cc'd on this
20 email. And it's from the same person,
21 Mr. Verma, and we're talking about
22 inventory here. He says Torrent has three
23 to four months of inventory left. What is
24 inventory?

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1 A. Inventory would refer to the
 2 amount of finished product we have in
 3 stock, kind of based on our average monthly
 4 selling quantity.
 5 Q. So that's in Torrent
 6 facilities, right, in your warehouses?
 7 A. Yes, that would be considered
 8 within Torrent, Torrent facilities or
 9 warehouses.
 10 Q. So did your company ever go to
 11 those warehouses, take a pill, and test
 12 that pill for NDMA on July 11, 2018?
 13 MS. NAGLE: Objection.
 14 Form and foundation.
 15 THE WITNESS: If the
 16 product is in the U.S., again, we
 17 didn't have the ability to test and
 18 weren't doing any testing. I can't
 19 really speak to whether on July 11
 20 anyone else took product from a
 21 Torrent facility and tested it.
 22 BY MS. PAPANTONIO:
 23 Q. All right. And in this same
 24 email, Verma is asking what are our

Page 219

1 timelines to test these impurities, right?
 2 So it looks like Torrent is trying to
 3 develop a way to test for these impurities,
 4 correct?
 5 A. Correct.
 6 Q. And then he further says to
 7 "validate our assumption that the ROD does
 8 not have an issue," right? Assumption
 9 means guess?
 10 MS. NAGLE: Objection,
 11 form.
 12 THE WITNESS: The email
 13 says to "validate our assumption."
 14 BY MS. PAPANTONIO:
 15 Q. And assumption means guess,
 16 right?
 17 MS. NAGLE: Objection to
 18 form.
 19 THE WITNESS: Yeah, I'm
 20 not a dictionary, sorry.
 21 BY MS. PAPANTONIO:
 22 Q. Well, so what this is saying is
 23 that Torrent is guessing that the old ROD
 24 does not have the issue, right?

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1 MS. NAGLE: Objection,
 2 form.
 3 THE WITNESS: No. It
 4 says that they are assuming that
 5 the old route of synthesis does not
 6 have an issue.
 7 BY MS. PAPANTONIO:
 8 Q. And that assumption is made on
 9 the facts that ZHP is providing Torrent at
 10 this time?
 11 MS. NAGLE: Objection.
 12 Form and foundation.
 13 THE WITNESS: I'm not
 14 sure what all that assumption is
 15 based on. It's at least partially
 16 on that data from ZHP.
 17 BY MS. PAPANTONIO:
 18 Q. Right. And so let's go back to
 19 the inventory, right. Torrent has got
 20 three to four months of inventory. How
 21 many pills is that?
 22 MS. NAGLE: Objection,
 23 foundation.
 24 THE WITNESS: I have no

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1 idea.
 2 BY MS. PAPANTONIO:
 3 Q. You don't how many patients
 4 three to four months of inventory can
 5 supply?
 6 MS. NAGLE: Objection,
 7 foundation.
 8 THE WITNESS: No.
 9 BY MS. PAPANTONIO:
 10 Q. But we do know that if you had
 11 tested this inventory on July 11, what you
 12 would have found is that it was
 13 contaminated with NDMA?
 14 MS. NAGLE: Objection.
 15 Form and foundation.
 16 THE WITNESS: I don't
 17 know that.
 18 BY MS. PAPANTONIO:
 19 Q. So at this point, July 11, this
 20 is now three weeks later from the ZHP
 21 notice of a genotoxic impurity, right?
 22 A. It is approximately three weeks
 23 after their initial notification to us.
 24 Q. And three weeks after the

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1 initial notification, Torrent has still not
 2 verified that there's no NDMA in their drug
 3 valsartan?
 4 MS. NAGLE: Objection,
 5 form.
 6 THE WITNESS: Again,
 7 that seems to be the case, based on
 8 the information here.
 9 BY MS. PAPANTONIO:
 10 Q. So then we can assume that for
 11 three weeks, you're still selling the drug
 12 valsartan?
 13 A. Yes.
 14 Q. We can assume that you're still
 15 telling customers that Torrent's valsartan
 16 is safe to use?
 17 MS. NAGLE: Objection,
 18 form.
 19 THE WITNESS: I don't
 20 know what was communicated to
 21 customers within those three weeks.
 22 BY MS. PAPANTONIO:
 23 Q. Well, at this point, you're
 24 communicating with the FDA that your

Page 223

1 product is still safe, right?
 2 MS. NAGLE: Objection,
 3 form.
 4 THE WITNESS: We can go
 5 back through some specific emails,
 6 but at this point, we have no
 7 information and no data to show
 8 that our product is containing the
 9 impurity.
 10 BY MS. PAPANTONIO:
 11 Q. And we can agree a way to get
 12 data is to test products?
 13 A. You can test products to get
 14 data, yes.
 15 Q. Right. So if you wanted data,
 16 you could test the valsartan?
 17 A. Again, the issue is whether our
 18 ability to test at this point actually
 19 would detect any of the impurity that was
 20 there.
 21 Q. So you're familiar with GC-MS
 22 testing, right?
 23 MS. NAGLE: Objection,
 24 foundation.

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1 THE WITNESS: Vaguely.
 2 BY MS. PAPANTONIO:
 3 Q. That's gas chromatography and
 4 mass spectrometry?
 5 A. Correct.
 6 Q. You're aware that they used
 7 GC-MS testing to determine that NDMA was in
 8 valsartan products?
 9 A. If that's -- at some point, we
 10 learned that was the method that was being
 11 used. I don't know what was -- what I knew
 12 at this point.
 13 Q. Are you aware that GC-MS
 14 testing has been around since the nineties?
 15 MS. NAGLE: Objection,
 16 form.
 17 THE WITNESS: It is a
 18 testing method that has been around
 19 a while, yes.
 20 BY MS. PAPANTONIO:
 21 Q. That for 30 years now companies
 22 have been able to test for nitrosamines
 23 using the GC-MS test method?
 24 MS. NAGLE: Objection,

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1 form.
 2 THE WITNESS: GC-MS is
 3 not a test method. Well, I talk
 4 about test method, it means that
 5 there's a very specific set of
 6 criteria that are used on that
 7 GC-MS that are specific to each
 8 drug product, specific to each API,
 9 for instance. So it's not as if
 10 there was a method in 1990 that
 11 existed to detect this impurity.
 12 That's completely false.
 13 BY MS. PAPANTONIO:
 14 Q. You had no idea that there was
 15 GC-MS testing of nitrosamines for the last
 16 30 years? That's not information that you
 17 knew?
 18 MS. NAGLE: Objection,
 19 form.
 20 THE WITNESS:
 21 Specifically of nitrosamines, no.
 22 BY MS. PAPANTONIO:
 23 Q. But you do know that Torrent
 24 internationally has labs across the world,

Page 226

1 right?

2 MS. NAGLE: Objection,

3 form.

4 THE WITNESS: I'm aware

5 of the labs that we used in

6 connection with the testing of

7 materials for our U.S. products.

8 BY MS. PAPANTONIO:

9 Q. Right, but Torrent, the

10 company, has its own laboratories that they

11 use to test the quality of their drugs,

12 right?

13 A. Torrent does have its own labs,

14 yes.

15 Q. They employ hundreds of

16 scientists to conduct these quality checks?

17 MS. NAGLE: Objection.

18 Form and foundation.

19 THE WITNESS: I can't

20 really say how many specifically,

21 but we have -- did have labs, yes.

22 BY MS. PAPANTONIO:

23 Q. Okay. So we're going to move

24 on later in this email. We can see that

Page 227

1 you are in this email dated July 11, but if

2 we go up to the first email on this page,

3 we see that you've actually been cut out of

4 this email. So I want to actually start,

5 because I want to see who is talking in

6 these emails. So let's go to this middle

7 email. So we know Jaiswal is in quality,

8 right?

9 A. I believe, I believe so. I

10 don't recall actual what his -- which group

11 he was working with at the manufacturing

12 facility, but.

13 Q. What about this next

14 individual? I'm not even going to try to

15 pronounce it.

16 A. Jayatibha is -- she was part of

17 the quality organization, yes.

18 Q. Also in the quality department.

19 We know that you were a part of the quality

20 department as well?

21 A. No, I'm not.

22 Q. Or regulatory department?

23 A. Regulatory and quality are two

24 different things. So I was part of the

Page 228

1 regulatory department.

2 Q. Okay. What about Modi?

3 A. Amit is in the U.S. office. He

4 was part of our supply chain team.

5 Q. Supply chain. And what about

6 Agrawal?

7 A. Vineet is also from the U.S.

8 office, I believe he was also in supply

9 chain with Amit.

10 Q. Okay. And then the next

11 person, Sekhar?

12 A. Sekhar, I believe, was from

13 either supply chain or procurement at the

14 India-based company.

15 Q. Okay. And then Sheth?

16 A. Same with Paras, she was based

17 in India, either with procurement or supply

18 chain.

19 Q. So in this email that we're

20 looking at now, we have all the quality

21 people, we've got supply chain people, and

22 procurement people, as well as you in the

23 regulatory department.

24 Now, the following email, they

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1 cut all those people out, right? And what

2 they're talking about, what we can see is

3 who is in this email chain, who is

4 Siddhaye?

5 A. I don't recall who that is.

6 The rest of the folks on the email chain

7 are either supply chain or sales in the

8 U.S.

9 Q. All right. So we go from

10 talking about quality to talking about

11 sales. And what this email says is asking

12 is "what is the annual budget sales and

13 margin impact if we were to discontinue all

14 valsartan-containing products?" Do you see

15 that?

16 A. Yes.

17 Q. So once your colleagues start

18 talking about money, you are cut out of the

19 email chain. Do you see that?

20 MS. NAGLE: Objection,

21 form.

22 THE WITNESS: I'm not on

23 this message, correct.

24

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1 BY MS. PAPANTONIO:
2 Q. And we can agree if Torrent
3 found something bad in its products that
4 that would ultimately affect sales, right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: It depends
8 on what action was taken, but
9 recalls do have an impact on sales.
10 BY MS. PAPANTONIO:
11 Q. If there was a potent
12 carcinogen found in the drug, it would
13 ultimately affect how that drug was sold?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: For any
17 reason, if we have to recall a
18 product, it impacts how that drug
19 is sold, yes.
20 BY MS. PAPANTONIO:
21 Q. In your time at Torrent, were
22 you ever aware that in the same breath,
23 your Torrent colleagues are talking about
24 safety and testing timelines, but there's

Page 231

1 also talking about losing money?
2 MS. NAGLE: Objection,
3 form.
4 THE WITNESS: So, you
5 know, Torrent is a business and all
6 of our actions have financial
7 implications, so the financial
8 piece is always a part of any
9 conversation related to quality
10 issues. It's never the most
11 important part of the conversation.
12 BY MS. PAPANTONIO:
13 Q. But we can agree the longer
14 that valsartan is on the market, the more
15 money Torrent makes?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: While
19 Torrent is selling a product, they
20 are making money.
21 BY MS. PAPANTONIO:
22 Q. And if Torrent discontinues a
23 product, they stop making money, right?
24 A. That product specifically, yes.

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1 Q. Okay. So let's see how much
2 money valsartan makes Torrent. Let's go to
3 the next -- or the first page now. Again,
4 in the second email, we've got all our
5 salespeople. And in this first line it
6 says "We sold around 11 mn tabs." Does
7 that mean 11 million tabs, tablets?
8 MS. NAGLE: Objection,
9 foundation.
10 THE WITNESS: In that
11 context, yes, it means 11 million
12 tabs.
13 BY MS. PAPANTONIO:
14 Q. Okay. So 11 million tablets
15 were given to customers in the year 2018?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: I'm not
19 sure what this year refers to,
20 which time frame, honestly, so.
21 BY MS. PAPANTONIO:
22 Q. Okay. And we do know that this
23 contamination happened between, let's say,
24 2014 and 2018?

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1 MS. NAGLE: Objection.
2 Form and foundation.
3 THE WITNESS: We were
4 first notified of the potential
5 impurity in June of 2018.
6 BY MS. PAPANTONIO:
7 Q. Okay. We'll talk about that
8 later. Okay. And it says total sales were
9 2.2 million, right? Do you see that?
10 A. I do see that.
11 Q. With a 52 percent gross margin.
12 Do you see that too?
13 A. Yes.
14 Q. Okay. So now earlier we were
15 talking about cheap Chinese API and that's
16 how Torrent had referred to ZHP. Do you
17 remember that?
18 A. I think it was referred to as
19 cheaper API.
20 Q. Cheaper API. And Torrent was
21 buying from ZHP in order to save money,
22 right?
23 MS. NAGLE: Objection,
24 form.

<p style="text-align: right;">Page 234</p> <p>1 THE WITNESS: As I had 2 said before, it's also a derisking 3 strategy. Most of our products 4 always had multiple API sources in 5 case of interruption at one 6 supplier or another. 7 BY MS. PAPANTONIO: 8 Q. Right. And what you also said 9 before is that Torrent is a business in the 10 business of making money, right? 11 A. I don't know that I said that, 12 but Torrent is a business and so the price 13 of our materials is always something that's 14 taken into consideration when we make 15 decisions. 16 Q. And cheap doesn't always mean 17 bad, right, Ms. Chitty? 18 A. Cheap does not always 19 necessarily mean bad, I would agree with 20 that. 21 Q. But it does mean that you have 22 to follow up and conduct due diligence on 23 those products? 24 MS. NAGLE: Objection,</p>	<p style="text-align: right;">Page 236</p> <p>1 THE WITNESS: No, 2 there's -- I can't draw any 3 conclusions that that would have 4 happened. 5 BY MS. PAPANTONIO: 6 Q. So Torrent is talking about 7 saving money here. Are you aware that it 8 only cost a couple of thousand dollars to 9 test for NDMA? 10 MS. NAGLE: Objection, 11 form. 12 THE WITNESS: No, I'm 13 not familiar with the cost 14 associated with testing of 15 products. 16 BY MS. PAPANTONIO: 17 Q. 1093. Okay. Let's do 1096. 18 Okay. Again, we're going to that -- we'll 19 stay on the first page. 20 MS. NAGLE: Sorry, 21 Counsel, could you let me what 22 exhibit number this is? 23 MS. PAPANTONIO: Oh, 24 sorry, Torrent 23.</p>
<p style="text-align: right;">Page 235</p> <p>1 form. 2 THE WITNESS: As we 3 discussed earlier, there's 4 procedures for procurement of any 5 of our materials that are followed 6 for whether it's API or whether 7 it's inactives. 8 BY MS. PAPANTONIO: 9 Q. You have to make sure that 10 cheap product you're getting is still a 11 quality product? 12 MS. NAGLE: Objection, 13 form. 14 THE WITNESS: We have to 15 make sure every product we get 16 meets standards that are in place 17 at the time. 18 BY MS. PAPANTONIO: 19 Q. Are you aware that if Torrent 20 would have tested one of these 11 million 21 pills with API from ZHP, they would have 22 found that it was contaminated with NDMA? 23 MS. NAGLE: Objection, 24 form.</p>	<p style="text-align: right;">Page 237</p> <p>1 MS. NAGLE: Thank you. 2 BY MS. PAPANTONIO: 3 Q. I apologize. Okay. We see 4 that this email is dated -- let's look at 5 the second email or third email. The one 6 from you, Dawn Chitty. And this is dated 7 July 17, right? 8 A. Yes. 9 Q. Now, this is almost a month 10 after your company learned that ZHP 11 valsartan was in fact contaminated? 12 MS. NAGLE: Objection, 13 form. 14 THE WITNESS: It's a 15 month after we were notified of a 16 new unknown impurity. 17 BY MS. PAPANTONIO: 18 Q. Okay. And this is on the 17th, 19 so I really want to take note of this date. 20 So July 17, we're having this conversation. 21 Okay. Let's talk about who these people 22 are in the email. I think we haven't met 23 Sumit Basu, who is that? 24 A. I do not recall who that is.</p>

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1 Q. Okay. Can't remember cc'ing
2 him on this email?
3 A. No.
4 Q. Okay. And so you are talking
5 to these people, it looks like we've got a
6 person in quality, two people in quality,
7 Patel and Jaiswal, right?
8 A. Yes.
9 Q. And you're talking, saying
10 "What method are they using to detect the
11 amounts in other routes of synthesis,"
12 right?
13 A. In the other route of
14 synthesis, yes.
15 Q. Right. You're asking what are
16 we doing to test?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: I'm not
20 sure who the "they" refers to, but
21 I'm asking about testing specifics
22 to try to detect the impurity.
23 BY MS. PAPANTONIO:
24 Q. Right. Because at this point,

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1 a month later, you understand the
2 importance of getting an answer to this
3 question of whether or not Torrent
4 valsartan is contaminated with NDMA?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: We are
8 definitely at this point all still
9 working towards having an accurate
10 ability to test for the impurity.
11 BY MS. PAPANTONIO:
12 Q. Right. And you're telling
13 colleagues in India, you're pushing them
14 and asking them what the methods are to
15 test, right?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: I am
19 asking about the method, correct.
20 BY MS. PAPANTONIO:
21 Q. And you're telling them that
22 the FDA is expecting that we're going to
23 prove that there's no NDMA in the API
24 batches that we've used, right?

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1 A. That is correct.
2 Q. Because you, in regulatory
3 affairs, have to communicate that
4 information to the FDA, right?
5 A. I have to communicate
6 information on risk, known risk to FDA,
7 correct.
8 Q. Right, because you understand
9 that Torrent as the ANDA holder, as the
10 finished dose manufacturer, has the
11 ultimate duty to make sure that your
12 product is safe, right?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: We have
16 the duty to confirm that it is
17 meeting specifications that are in
18 place at the time.
19 BY MS. PAPANTONIO:
20 Q. But you have to ensure that
21 Torrent's drug is not hurting people?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: Again,

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1 it's not about determining safety
2 or hurting people. That's a
3 benefit-risk analysis, like I
4 mentioned before. Nothing is
5 without risk. It has to be looked
6 at singularly for each product and
7 each person.
8 BY MS. PAPANTONIO:
9 Q. But you're ultimately the
10 person communicating that information to
11 the FDA. They're relying on you, right?
12 A. I am the liaison between
13 Torrent and FDA, yes.
14 Q. And you say "They are not going
15 to let us release any product unless
16 there's conclusive proof," right?
17 A. That's what the message says,
18 yes.
19 Q. And that's reasonable?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: Was that a
23 question or a statement?
24

<p>Page 242</p> <p>1 BY MS. PAPANTONIO: 2 Q. Right, you want to ensure that 3 the product you are selling is actually 4 safe? 5 MS. NAGLE: Objection, 6 form. 7 THE WITNESS: We are 8 wanting to make sure the product 9 we're selling is meeting current 10 specifications, yes. 11 BY MS. PAPANTONIO: 12 Q. And that statements from the 13 vendor are not sufficient, right? The 14 vendor in this case is ZHP, correct? 15 A. The vendor is ZHP. 16 Q. So you're telling your 17 colleagues that we can't trust what ZHP is 18 saying is true, right? 19 MS. NAGLE: Objection, 20 form. 21 THE WITNESS: I don't 22 believe that's the intent here. 23 You know, my intent is I would like 24 a second piece of data to confirm</p> <p>Page 243</p> <p>1 what we're hearing from ZHP. 2 BY MS. PAPANTONIO: 3 Q. Right. You want to be 4 absolutely sure that the product that 5 you're providing does not have NDMA in it? 6 MS. NAGLE: Objection, 7 form. 8 THE WITNESS: Again, 9 yes, we are all agreeing within 10 Torrent that we need to have some 11 testing around this and develop the 12 appropriate methods. 13 BY MS. PAPANTONIO: 14 Q. Well, let's see if you guys are 15 agreeing, but first I want to talk about 16 this last sentence. It says "We need to 17 get this verified as soon as possible." 18 Would you agree with that statement? 19 A. I'm sorry, I'm just moving my 20 screen around here. "We need to get this 21 verified/validated as soon as possible." 22 That is what the email says. 23 Q. Right, so you are telling your 24 Indian Torrent colleagues, we have to get a</p>	<p>Page 244</p> <p>1 method validated, right? 2 A. Correct, that is my opinion. 3 Q. That we need additional 4 evidence in addition to ZHP's statements? 5 MS. NAGLE: Objection. 6 THE WITNESS: Correct. 7 BY MS. PAPANTONIO: 8 Q. And now you've just told us 9 that everyone at Torrent was on board with 10 those statements that you were making, so 11 let's look at the next email from Verma. 12 Now, remind me who Verma is again? 13 A. Arun is the chief operating 14 officer for the U.S. Torrent-based company. 15 Q. Okay. So we've got the guy who 16 is responsible for the money talking now, 17 right? 18 A. He oversees supply chain as 19 well as other operational activities. 20 Q. Okay. And Arun says that "All 21 customers have been back-ordered." Do you 22 see that? 23 A. Yes. 24 Q. "And every single day counts."</p> <p>Page 245</p> <p>1 Do you see that? 2 A. Yes. 3 Q. "Our failure to supply 4 penalties will start kicking in, so the 5 earlier we submit data to the FDA," right? 6 A. That is what the email says, 7 yes. 8 Q. So at this point, your company 9 could be facing millions of dollars of 10 supply penalties, right, if they don't get 11 valsartan back on the market? 12 MS. NAGLE: Objection. 13 Form and foundation. 14 THE WITNESS: I'm really 15 not aware of what those penalties 16 are. 17 BY MS. PAPANTONIO: 18 Q. But you know that your COO is 19 saying that every single day counts? 20 A. That is what the email says. 21 Q. Right, if we continue to fail 22 to supply valsartan, then penalties will 23 start kicking in? 24 A. Correct, so there are certain</p>
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1 penalties in certain agreements with
 2 customers.
 3 Q. But nowhere in here does he
 4 say, yes, Dawn, you're correct, let's test
 5 this product to verify?
 6 A. He, again, is a more
 7 business-focused person. He's aware that
 8 the quality team is working on this and so
 9 just in this email, he is focused on more
 10 of the financial aspects of the situation.
 11 It does --
 12 Q. And in this -- excuse me,
 13 sorry, go ahead.
 14 A. I was going to say, it does not
 15 mean that the other quality aspects are
 16 still not being considered by the
 17 appropriate people involved.
 18 Q. Well, so in the same breath
 19 that you were talking about the importance
 20 of testing the drug, he's talking about the
 21 penalties that Torrent faces, right, if
 22 they don't get the drug back on the market?
 23 MS. NAGLE: Objection,
 24 form.

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1 THE WITNESS: Again,
 2 that is his focus and job within
 3 the company.
 4 BY MS. PAPANTONIO:
 5 Q. And if we had tested the
 6 Torrent valsartan on this date, July 17,
 7 you would have found that NDMA was present
 8 in Torrent valsartan?
 9 MS. NAGLE: Objection,
 10 form.
 11 THE WITNESS: Again,
 12 testing at this date with a method
 13 that's not appropriate to detect
 14 that impurity would not have
 15 necessarily detected it.
 16 BY MS. PAPANTONIO:
 17 Q. If they had listened to you,
 18 Ms. Chitty, and actually taken steps to
 19 develop a method on this date, July 17,
 20 they would have found that Torrent's
 21 valsartan was contaminated with a potent
 22 carcinogen, right?
 23 MS. NAGLE: Objection.
 24 Form and foundation.

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1 THE WITNESS: So I don't
 2 believe, number one, that they
 3 are -- they were not listening to
 4 me. I know they were working on
 5 this diligently. And developing a
 6 method is just not something you do
 7 overnight. Especially, this type
 8 of method, I understand, is
 9 complex, to be able to detect
 10 something at those very, very small
 11 quantities that these impurities
 12 were occurring at.
 13 MS. PENDLEY: Okay. I
 14 want to look at LP 1143. This will
 15 be marked Torrent 90.
 16 -----
 17 (FDA News Release marked Torrent
 18 Exhibit 90 for identification.)
 19 -----
 20 BY MS. PAPANTONIO:
 21 Q. Okay. We can see that this is
 22 the FDA announcement of the recall for
 23 valsartan drugs, right?
 24 A. Yes, that's what this appears

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1 to be.
 2 Q. This recall was on July 13,
 3 2018?
 4 A. That is the date of the press
 5 release, yes.
 6 Q. And so that means that is the
 7 day that all of the products were recalled?
 8 MS. NAGLE: Objection.
 9 Form and foundation.
 10 THE WITNESS: That will
 11 be the date that the information
 12 here is referring to. I don't know
 13 what all the products means, but --
 14 BY MS. PAPANTONIO:
 15 Q. I'm sorry, I'll clarify that in
 16 a minute. So we see that the FDA is saying
 17 in this first paragraph that this recall is
 18 due to an impurity, NDMA, which was found
 19 in the recalled products. Right?
 20 A. Correct. That's what it says.
 21 Q. And that NDMA is classified as
 22 a probable human carcinogen?
 23 A. Correct.
 24 Q. And, okay, and then if we go to

<p style="text-align: right;">Page 250</p> <p>1 the next page, we see all of the 2 manufacturers who had to recall their 3 product? 4 A. As of this date, these were the 5 manufacturers that were recalling product, 6 yes. 7 Q. Major Pharmaceuticals recalled 8 their valsartan, right? 9 A. Yes, according to this. 10 Q. Solco Healthcare, are you 11 familiar with them? 12 A. I'm familiar with the same. 13 Q. Are you familiar with Teva? 14 A. Yes. 15 Q. Okay. So five manufacturers 16 had to recall their valsartan due to the 17 presence of NDMA, right? 18 MS. NAGLE: Objection, 19 form. 20 THE WITNESS: Right 21 here, there's three manufacturers, 22 it looks like. 23 BY MS. PAPANTONIO: 24 Q. Oh, right, because this is just</p>	<p style="text-align: right;">Page 252</p> <p>1 So that's why I say I don't know who was 2 testing these products. Somebody was 3 testing these products. 4 Q. So we know that on July 13 5 someone was able to develop a test to find 6 NDMA in these three manufacturers' product? 7 A. And it was probably FDA. We 8 had some communication from FDA around the 9 similar time frame that they had developed 10 a method to test for NDMA, but had not 11 shared the details of that testing method 12 with Torrent. 13 Q. Ms. Chitty, at what point did 14 Torrent send samples to the FDA and say we 15 want to know if our product is safe, please 16 test it now? 17 MS. NAGLE: Objection, 18 form. 19 THE WITNESS: FDA 20 requested samples from us at 21 various time points. So we could 22 go back through those 23 communications. I don't recall 24 exactly when it was we were</p>
<p style="text-align: right;">Page 251</p> <p>1 a different form of valsartan. Okay. 2 Three manufacturers were able to test their 3 product and determine that NDMA was present 4 in their product on July 13? 5 MS. NAGLE: Objection. 6 Form and foundation. 7 THE WITNESS: It's 8 unclear who was testing products or 9 why they were recalled at this 10 point. So I can't conclude that 11 Major, Solco, and Teva were testing 12 their own products at this point. 13 BY MS. PAPANTONIO: 14 Q. We know that these products 15 were recalled because of the presence of 16 NDMA, right? 17 A. Presumably, as explained in 18 this letter, that's why they were recalled. 19 Q. But in order to know there's 20 NDMA in the products, you have to test the 21 product, right? 22 A. Someone has to test the 23 products and as you guys are aware, FDA had 24 been requesting and testing samples also.</p>	<p style="text-align: right;">Page 253</p> <p>1 providing samples, because we 2 provided multiple sets of samples. 3 BY MS. PAPANTONIO: 4 Q. At what point did Torrent USA 5 contact Major Pharmaceuticals and say who 6 tested your API, we want to know if our 7 product is safe? 8 MS. NAGLE: Objection, 9 form. 10 THE WITNESS: I'm not 11 aware if anyone within Torrent 12 contacted Major. 13 BY MS. PAPANTONIO: 14 Q. Not aware of anyone from 15 Torrent contacting Solco Healthcare and 16 saying, hey, guys, can we borrow your 17 method so we can determine whether or not 18 our drug has NDMA in it? 19 MS. NAGLE: Objection, 20 form. 21 THE WITNESS: I'm not 22 aware, and again, as I had 23 mentioned before, methods are 24 actually very specific to drug</p>

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1 products. So for instance, if
2 Solco added different inactive
3 ingredients than what Torrent had,
4 those methods may not work on other
5 people's products, because of the
6 differences in inactives and things
7 like that. Methods tend to be very
8 specific to the drug product or the
9 API at hand.

10 BY MS. PAPANTONIO:
11 Q. And we can agree in order to
12 find out a manufacturer's method, you have
13 to ask the question?

14 MS. NAGLE: Objection.
15 MS. PAPANTONIO: Right?
16 THE WITNESS: I would
17 agree you have to ask a question to
18 get an answer. But talking to
19 other manufacturers about
20 proprietary information is not
21 something I'm aware of as being
22 common in the pharma industry.

23 BY MS. PAPANTONIO:
24 Q. So talking to manufacturers in

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1 an effort to save patients is not common in
2 the manufacturing industry, pharmaceutical
3 industry?

4 MS. NAGLE: Objection,
5 form.

6 THE WITNESS: Talking
7 about saving patients is, you know,
8 I don't know what that -- don't
9 know what that means. But
10 companies typically do not share
11 proprietary information with each
12 other, so.

13 BY MS. PAPANTONIO:
14 Q. But what we do know at this
15 point is that Torrent, you're not aware of
16 Torrent ever asking for their methods on
17 how to test the NDMA?

18 A. I personally am not aware. It
19 doesn't mean it didn't happen. It just
20 means that I'm personally not aware of it.

21 Q. Okay. Let's look at LP 1108.
22 And this will be Torrent 91.
23 -----
24 (Email String Bates

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1 TORRENT-MDL2875-00504801 marked
2 Torrent Exhibit 91 for
3 identification.)
4 -----
5 BY MS. PAPANTONIO:
6 Q. Okay. We're going to go to
7 page 3. Okay. You remember that in the
8 email we just looked at a minute ago, you
9 were talking about testing the product on
10 July 17, right?

11 A. Correct.

12 Q. You were telling your
13 colleagues that it's important we test the
14 valsartan to verify what ZHP is saying is
15 true. Do you remember that?

16 A. Correct.

17 Q. Do you remember saying that the
18 statements from the vendor, ZHP, were not
19 sufficient?

20 A. Correct, I was requesting
21 additional information.

22 Q. Right. So this is on the same
23 day that you were telling your colleagues
24 we need to test the product, July 17,

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1 looking at that last email on this page?
2 A. Yeah, I believe that's the same
3 day.

4 Q. Okay. Let's blow that up. And
5 on this day, you're talking back and forth
6 with the FDA, right?

7 A. Correct.

8 Q. That's an FDA email address?
9 A. Yes.

10 Q. Okay. You understand that the
11 FDA relies on the information that Torrent
12 USA gives them, right?

13 MS. NAGLE: Object to
14 form.

15 THE WITNESS: Yes, they
16 rely on our information.

17 BY MS. PAPANTONIO:
18 Q. And you understand that,
19 ultimately, it's not the FDA's job to tell
20 Torrent that their product is safe?

21 MS. NAGLE: Objection,
22 form.

23 THE WITNESS: I don't
24 think I agree with that statement.

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1 BY MS. PAPANTONIO:
2 Q. You know it's ultimately not
3 the FDA's job to tell Torrent that their
4 product is a quality product?
5 MS. NAGLE: Objection to
6 form.
7 THE WITNESS: It is the
8 FDA's job to monitor those things.
9 BY MS. PAPANTONIO:
10 Q. And it's Torrent's job to
11 create a quality product, right?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: Correct.
15 BY MS. PAPANTONIO:
16 Q. Okay. So looking at this
17 letter, we see you're talking with the FDA
18 and you say "We contacted customers by
19 email on Thursday of last week, July 12.
20 Here's the basic text of our message." So
21 the message below is what you're
22 communicating to customers, right?
23 A. Yes, that's what that seems to
24 be.

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1 Q. This is the information that
2 you're giving them on the potential
3 impurity?
4 A. Correct.
5 Q. And in this letter, you inform
6 customers that ZHP, your API manufacturer,
7 has notified us, Torrent, that the impurity
8 is isolated in one route of synthesis,
9 right. Do you see that?
10 A. Yes.
11 Q. And then you say that "There
12 are no Torrent products in the U.S. that
13 use this route of synthesis where the
14 impurity is identified," right?
15 A. Yeah, I'm just waiting for the
16 rest of the text to come up. Correct.
17 Q. So you're parroting the
18 information that ZHP gave you to your
19 customers, right?
20 A. We are communicating what we
21 know at this time to our customers.
22 Q. And that's because at this
23 point, Torrent is still operating under the
24 assumption that ZHP is correct?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: We are
4 considering the information that we
5 have at the time, which is
6 information from ZHP.
7 BY MS. PAPANTONIO:
8 Q. Well, you're not just
9 considering it, Ms. Chitty, you're actually
10 telling that information to your customers?
11 A. We are transmitting, again, the
12 information we have at our -- at that time
13 to our customers.
14 Q. And you're transmitting the
15 information from ZHP, because at this time,
16 on July 17, you still have no way to test
17 the product and verify the information from
18 ZHP?
19 MS. NAGLE: Objection,
20 form.
21 THE WITNESS: At this
22 point in time, we did not have a
23 method to be able to test those
24 products specifically for that

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1 impurity.
2 BY MS. PAPANTONIO:
3 Q. Okay. So you were providing
4 the FDA in this email with a -- well, you
5 sent a copy of this message to the FDA,
6 right, which you had sent to your
7 customers?
8 A. Correct.
9 Q. Okay. And you are telling the
10 FDA, based on what we know from ZHP, our
11 valsartan has not been affected by this
12 recall, right?
13 A. Correct.
14 Q. You're giving -- Torrent is
15 giving assurances to the FDA that their
16 product is safe?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: We are
20 sharing, again, the data and
21 information that we have at the
22 time and have no reason to second
23 guess.
24

<p style="text-align: right;">Page 262</p> <p>1 BY MS. PAPANTONIO: 2 Q. Right. And on the same day, 3 you were telling colleagues that statements 4 from your vendor, ZHP, weren't sufficient, 5 you're telling the FDA and your customers 6 that there's no NDMA in our product? 7 MS. NAGLE: Objection, 8 form. 9 THE WITNESS: Those 10 communications did happen on the 11 same day, yes. 12 BY MS. PAPANTONIO: 13 Q. And on the -- go ahead. 14 A. No, go ahead. 15 Q. And on the same day that your 16 COO, chief operating officer, is saying 17 that we can't wait anymore, that there's 18 penalties that are going to be invoked, 19 you're telling your customers and the FDA 20 that your product is safe? 21 MS. NAGLE: Objection, 22 form. 23 THE WITNESS: So we are 24 sharing information that it doesn't</p>	<p style="text-align: right;">Page 264</p> <p>1 as our failure supply penalties will start 2 kicking in." Page 1 of 23, Torrent 23. 3 Highlight that that's on the 18th. 4 Okay. And then on the same 5 day, July 18, you're asking the FDA at this 6 very top email on page 3, Are we able to 7 release our valsartan products for 8 quarantine at this time? Do you see that? 9 A. Yes, I see that. 10 Q. And the same day your chief 11 operating officer is saying how quickly you 12 have to get valsartan back on the market, 13 you are asking FDA to release the product? 14 MS. NAGLE: Objection, 15 form. 16 THE WITNESS: At this 17 point, again, we have no data to 18 suggest that the products we have 19 in quarantine are impacted. 20 BY MS. PAPANTONIO: 21 Q. And you have no data, because 22 you've never tested the product yourself to 23 validate what ZHP is telling you is true, 24 right?</p>
<p style="text-align: right;">Page 263</p> <p>1 seem like our products are 2 impacted. We're also communicating 3 that we're taking steps to hold 4 products while we're waiting for 5 additional information. 6 BY MS. PAPANTONIO: 7 Q. You know what, actually, I want 8 to do a side by side of this. Can we pull 9 up LP 1096? All right. Let's do page 1 of 10 1096. Let's highlight that second email. 11 So, Ms. Chitty, I just want to make sure 12 I'm getting this right and make sure I know 13 the information that you're communicating. 14 On the same day your COO says failure to 15 supply and penalties will kick in, right, 16 that's on 1096? 17 MS. NAGLE: Sorry, 18 Counsel, do you mind just using the 19 exhibit numbers? That might make 20 things a little easier. 21 BY MS. PAPANTONIO: 22 Q. Torrent 23. So let's highlight 23 that email where your chief operating 24 officer is saying "Every single day counts</p>	<p style="text-align: right;">Page 265</p> <p>1 MS. NAGLE: Objection, 2 form. 3 THE WITNESS: At this 4 point, the method has not been 5 developed to accurately detect or 6 measure the NDMA. 7 BY MS. PAPANTONIO: 8 Q. And based on the information 9 that you are giving your customers and the 10 information that you're giving the FDA, the 11 FDA relies on that, right, and they allow 12 you to release the product? 13 MS. NAGLE: Objection, 14 form. 15 THE WITNESS: I do not 16 know if the FDA allows us to 17 release. 18 BY MS. PAPANTONIO: 19 Q. All right, let's only go back 20 to Torrent 91, page 2. All right. And 21 this last email, based on the information 22 and assurances that Torrent provided the 23 FDA, they allowed Torrent to release 24 valsartan back on the market, correct?</p>

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1 MS. NAGLE: Objection.
2 Form and foundation.
3 THE WITNESS: This is
4 telling us we can release whatever
5 is discussed above.
6 BY MS. PAPANTONIO:
7 Q. Based on the information that
8 you had provided to the FDA, information
9 saying that your process was not affected,
10 correct?
11 MS. NAGLE: Same
12 objections.
13 THE WITNESS: So we are
14 providing information to FDA, yes,
15 based on data we have in hand at
16 the time. FDA also is getting data
17 from ZHP and other sources, as well
18 as doing their own testing. So
19 it's not, I would believe, a sole
20 decision based on what we're
21 saying. It's a collective decision
22 based on all of the information FDA
23 may have and I don't know what all
24 that was.

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1 BY MS. PAPANTONIO:
2 Q. Ms. Chitty, don't you think
3 that a method should have been validated
4 before you asked the FDA to release your
5 product?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: Not
9 necessarily. Again, based on data
10 in hand at the time, there was no
11 reason to not sell the product.
12 There was no data indicating that
13 these batches contained the
14 impurity.
15 BY MS. PAPANTONIO:
16 Q. Again, let me back us up.
17 There was no data, because there was no
18 test method?
19 A. Is that a question?
20 Q. Yes.
21 A. There was no data, because the
22 method was not yet developed to a state to
23 where it would give us accurate data on
24 whether the impurity was present at this

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1 point.
2 Q. And you don't think that
3 Torrent should have tested the product to
4 see if it was contaminated with NDMA and
5 NDEA before releasing that product back
6 onto the market?
7 MS. NAGLE: Objection to
8 form.
9 THE WITNESS: That's not
10 what I said. We didn't have the
11 ability to test accurately at this
12 point as far as I was aware of.
13 BY MS. PAPANTONIO:
14 Q. And so it's your -- so you
15 didn't believe that Torrent should wait
16 until they had the ability to test for NDMA
17 and NDEA before releasing that product onto
18 the market?
19 MS. NAGLE: Objection to
20 form.
21 THE WITNESS: At this
22 point, the data we had did not give
23 us any indication to not sell. We
24 were pushing for more information,

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1 but all of the various data pieces
2 that we had at this date just gave
3 no indication that the impurity was
4 present.
5 BY MS. PAPANTONIO:
6 Q. It gave no indication, because
7 there was no test, Ms. Chitty, the test
8 that you were pushing your company,
9 Torrent, to take, right?
10 MS. NAGLE: Objection to
11 form.
12 THE WITNESS: We were
13 all aware that an appropriate
14 method had to be developed so
15 additional data could be generated.
16 BY MS. PAPANTONIO:
17 Q. Ms. Chitty, on this very day,
18 July 18, you're telling Torrent, we've got
19 to test this product for NDMA and NDEA,
20 right?
21 MS. NAGLE: Objection,
22 form.
23 THE WITNESS: I am
24 telling them, as I said in my

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1 email, that we should confirm the
2 results and have our --
3 BY MS. PAPANTONIO:
4 Q. So then you --
5 A. -- and have our own method in
6 place.
7 Q. So then you believe,
8 Ms. Chitty, that you should have validated
9 the procedure and tested for NDMA before
10 releasing that market on the market?
11 MS. NAGLE: Objection,
12 form.
13 BY MS. PAPANTONIO:
14 Q. That's reasonable?
15 A. No, that's not what I said and
16 that's not how we acted.
17 MS. PAPANTONIO: All
18 right. Are we ready to take a
19 ten-minute break?
20 MS. NAGLE: Sure.
21 THE WITNESS: Sure.
22 THE VIDEOGRAPHER: Okay.
23 3:03, we are off the video record.
24 - - - - -

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1 (A recess was taken at this time.)
2 - - - - -
3 THE VIDEOGRAPHER: 3:19,
4 we are on the video record.
5 BY MS. PAPANTONIO:
6 Q. All right. Ms. Chitty, are you
7 there?
8 A. Yeah, I'm here.
9 Q. All right. I couldn't see your
10 screen. Okay. I really just want to make
11 sure we have a clear understanding for the
12 jury of what this timeline looks like for
13 Torrent. Okay. So I just want to walk
14 through this step by step. What we know is
15 that on June 20, Torrent got a notification
16 from ZHP that there's a potentially
17 genotoxic impurity in valsartan, right?
18 A. I don't remember the exact
19 wording, but they were notified of an --
20 I'm sorry, unidentified impurity that was,
21 I think, potentially genotoxic.
22 Q. Right. And so sometime during
23 that time, the FDA had instructed Torrent
24 to quarantine their batches, right?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: I don't
4 recall whether that was an FDA
5 instruction or whether that was a
6 Torrent decision.
7 BY MS. PAPANTONIO:
8 Q. Okay. But regardless,
9 Torrent's products were in quarantine for a
10 period of time while Torrent was trying to
11 figure out whether or not this genotoxic
12 impurity affected their valsartan, right?
13 A. Correct.
14 Q. So from the June 20 to the
15 July 17 email with the FDA that we were
16 looking at, Torrent is trying to determine
17 whether or not NDMA or NDEA is in the
18 valsartan product, correct?
19 MS. NAGLE: Objection,
20 form.
21 THE WITNESS: During
22 the -- during that time frame,
23 we're continuing to gather
24 information. I think at the early

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1 part when we were first notified,
2 we didn't even know what the
3 potential impurity was.
4 BY MS. PAPANTONIO:
5 Q. Right.
6 A. You can't test for something
7 you don't really know what it is or where
8 it occurs, so.
9 Q. And in the month you're
10 learning of that impurity is actually NDMA,
11 Torrent has to make a decision of whether
12 or not they release their product to the
13 public or keep that product in quarantine,
14 right?
15 MS. NAGLE: Objection to
16 form.
17 THE WITNESS: That is a
18 Torrent decision unless we are
19 instructed by a regulator to take
20 some action in the meantime.
21 BY MS. PAPANTONIO:
22 Q. Right. And what we know based
23 on the documents we just saw that during
24 that time, three other manufacturers had

<p style="text-align: right;">Page 274</p> <p>1 recalled their product because they had 2 tested it and it had NDMA in the valsartan. 3 Do you remember seeing that document? 4 A. I remember seeing the recall 5 notification and I remember mentioning that 6 we don't know who tested that product, but 7 there apparently was some data to indicate 8 that the NDMA was present in those finished 9 drug products at those manufacturers. 10 Q. And so during that time, 11 Torrent is relying on the data from ZHP 12 which suggests that Torrent's product is 13 not affected by NDMA, right? 14 A. Torrent is evaluating that data 15 and also working to understand our own 16 method and develop our own method to be 17 able to also test for the impurity. 18 Q. And Torrent, like we said, 19 during this time does not have the ability 20 to test the product itself, so they're 21 relying on the assurances from ZHP that 22 their product is not affected by NDMA, 23 right? 24 MS. NAGLE: Objection,</p>	<p style="text-align: right;">Page 276</p> <p>1 we have to test the product? Do you 2 remember saying that? 3 MS. NAGLE: Objection, 4 form. 5 THE WITNESS: Yes, I was 6 encouraging our team to continue to 7 gather more additional data on the 8 situation. 9 BY MS. PAPANTONIO: 10 Q. So, Ms. Chitty, my question, 11 what I'm really trying to understand is if 12 you could not test the product to determine 13 NDMA wasn't present, why would you not just 14 wait until you could test the product? 15 MS. NAGLE: Objection, 16 form. 17 THE WITNESS: Wait in 18 what manner? 19 BY MS. PAPANTONIO: 20 Q. When Torrent is deciding 21 whether or not to keep their product in 22 quarantine or they release it back on the 23 market, why did Torrent not just wait until 24 they could test the product themselves and</p>
<p style="text-align: right;">Page 275</p> <p>1 form. 2 THE WITNESS: During 3 this time, Torrent does not yet 4 have a method to detect the 5 impurity and are taking into 6 consideration the data and the 7 information that ZHP is sharing. 8 BY MS. PAPANTONIO: 9 Q. Right. And like we saw in 10 earlier documents, Torrent is assuming that 11 the information ZHP is giving them is 12 accurate? 13 MS. NAGLE: Objection, 14 form. 15 THE WITNESS: I think 16 we're -- we were taking the 17 information as it was given and, 18 again, continuing to work to try 19 and verify for ourselves. 20 BY MS. PAPANTONIO: 21 Q. And do you remember that during 22 this period of time, you're communicating 23 to your colleagues and saying that the 24 statements from ZHP are not sufficient, but</p>	<p style="text-align: right;">Page 277</p> <p>1 validate that there was no NDMA in their 2 valsartan? 3 MS. NAGLE: Objection. 4 Form and foundation. 5 THE WITNESS: We have to 6 rely on data from our suppliers. 7 You know, that's kind of a big step 8 in what we do, right? We don't 9 verify every single little piece of 10 information that comes from 11 suppliers. There are times when we 12 gather our own additional 13 information and this was an 14 important situation, which is why I 15 was suggesting that we should go 16 ahead and continue to try and 17 gather our own data on this 18 situation. 19 BY MS. PAPANTONIO: 20 Q. I understand that you were 21 trying to do the right thing, Ms. Chitty, 22 and you were telling your company that this 23 is the right thing to do, but why did 24 Torrent not do the right thing? Why did</p>

<p style="text-align: right;">Page 278</p> <p>1 they not wait to release the product until</p> <p>2 they could test it themselves?</p> <p>3 MS. NAGLE: Objection.</p> <p>4 Form and foundation.</p> <p>5 THE WITNESS: It's not a</p> <p>6 matter of Torrent not doing the</p> <p>7 right thing or Torrent not working</p> <p>8 to the same goal that I had of</p> <p>9 having our own test method. To my</p> <p>10 knowledge, those activities were</p> <p>11 going on in parallel.</p> <p>12 BY MS. PAPANTONIO:</p> <p>13 Q. So if those activities were</p> <p>14 going on, then you would only have to wait</p> <p>15 a few short days longer until Torrent could</p> <p>16 verify that their product was not</p> <p>17 containing a carcinogen?</p> <p>18 MS. NAGLE: Objection.</p> <p>19 Form and foundation.</p> <p>20 THE WITNESS: I don't</p> <p>21 know what the time frame would have</p> <p>22 been. I don't think we had an</p> <p>23 estimate of how long it was going</p> <p>24 to take us to have an appropriate</p>	<p style="text-align: right;">Page 280</p> <p>1 it was linked to the route of</p> <p>2 synthesis we had been using in our</p> <p>3 products.</p> <p>4 BY MS. PAPANTONIO:</p> <p>5 Q. But why didn't you just test</p> <p>6 the route of synthesis to verify that the</p> <p>7 NDMA was not in your products?</p> <p>8 MS. NAGLE: Objection.</p> <p>9 Form and foundation.</p> <p>10 THE WITNESS: Can you</p> <p>11 repeat that question, I'm sorry?</p> <p>12 BY MS. PAPANTONIO:</p> <p>13 Q. Why did you just -- why didn't</p> <p>14 you just wait to release the product? Why</p> <p>15 didn't you test it yourself?</p> <p>16 MS. NAGLE: Same</p> <p>17 objections.</p> <p>18 THE WITNESS: Same</p> <p>19 answer. We were working to try and</p> <p>20 test it ourselves, but there was no</p> <p>21 data in hand to indicate the</p> <p>22 product could not be sold at that</p> <p>23 time.</p> <p>24</p>
<p style="text-align: right;">Page 279</p> <p>1 method and you don't -- it's not</p> <p>2 standard to take action on</p> <p>3 something based on a theoretical</p> <p>4 situation. You know, we make</p> <p>5 decisions based on data and we were</p> <p>6 making decisions based on the data</p> <p>7 we had in hand.</p> <p>8 BY MS. PAPANTONIO:</p> <p>9 Q. Ms. Chitty, you understand that</p> <p>10 this isn't a theoretical scenario, that</p> <p>11 NDMA is a carcinogen and was linked to</p> <p>12 valsartan, you understand that, right?</p> <p>13 MS. NAGLE: Objection,</p> <p>14 form.</p> <p>15 THE WITNESS: It was</p> <p>16 linked to certain types of</p> <p>17 valsartan.</p> <p>18 BY MS. PAPANTONIO:</p> <p>19 Q. And it was potentially linked</p> <p>20 to Torrent valsartan, right?</p> <p>21 MS. NAGLE: Objection,</p> <p>22 form.</p> <p>23 THE WITNESS: At that</p> <p>24 time, no, we had no indication that</p>	<p style="text-align: right;">Page 281</p> <p>1 BY MS. PAPANTONIO:</p> <p>2 Q. Is it true that you were</p> <p>3 worried about penalties at that time and</p> <p>4 that's the reason you didn't test to verify</p> <p>5 there was NDMA in your product?</p> <p>6 MS. NAGLE: Objection,</p> <p>7 form.</p> <p>8 THE WITNESS: For</p> <p>9 myself, there was not the</p> <p>10 consideration of penalties going</p> <p>11 into any of the decision-making</p> <p>12 that I was doing or suggestions</p> <p>13 that I was making.</p> <p>14 BY MS. PAPANTONIO:</p> <p>15 Q. But your COO understood that</p> <p>16 the longer you wait to release valsartan,</p> <p>17 that the more penalties would kick in. Do</p> <p>18 you remember him saying that?</p> <p>19 MS. NAGLE: Objection,</p> <p>20 form.</p> <p>21 THE WITNESS: He did --</p> <p>22 he was considering that, obviously,</p> <p>23 by his, by his emails, but again,</p> <p>24 the money aspects were not driving</p>

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1 the quality decisions.
2 BY MS. PAPANTONIO:
3 Q. Well, they were driving the
4 quality decisions, because you understand
5 that you were telling your customers that
6 the statements from ZHP weren't sufficient,
7 we have to test the drug. But instead, you
8 released it. So why didn't you wait to
9 test the drug?
10 MS. NAGLE: Objection.
11 Form and foundation.
12 THE WITNESS: And I'm
13 not sure that we were telling our
14 customers that the data wasn't
15 sufficient either.
16 BY MS. PAPANTONIO:
17 Q. Ms. Chitty, do you understand
18 that with every day that goes by, patients
19 are taking your drug?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: Patients
23 take our products every day, yes.
24

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1 BY MS. PAPANTONIO:
2 Q. And with every day that went by
3 here, patients were taking a product that
4 had NDMA in it?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: We did not
8 know at that time that the products
9 contained NDMA.
10 BY MS. PAPANTONIO:
11 Q. And that when you released that
12 product back on to the market, you were
13 actually releasing a contaminated
14 valsartan?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: We did not
18 know at the time the products were
19 released to the market that they
20 did not meet specifications.
21 BY MS. PAPANTONIO:
22 Q. You had no idea that when
23 Torrent decided that they wanted to save
24 money and release the valsartan API that

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1 customers were actually getting -- taking
2 drugs with NDMA in them?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: There was
6 no knowledge at that time that
7 there was NDMA present in those
8 products.
9 BY MS. PAPANTONIO:
10 Q. There was no knowledge that
11 NDMA was present, because you never tested
12 the drug to determine it was present?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: We weren't
16 able to test to detect those small
17 levels of NDMA if they were present
18 at that time that the batches were
19 released.
20 BY MS. PAPANTONIO:
21 Q. If you had not released -- do
22 you understand that when you release this
23 product back on the market that you were
24 releasing valsartan that was 400 times the

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1 FDA threshold limit for NDMA?
2 MS. NAGLE: Objection,
3 form.
4 THE WITNESS: As I said,
5 we had no knowledge at the time of
6 release that there was NDMA present
7 in any of those batches.
8 BY MS. PAPANTONIO:
9 Q. Do you understand that had you
10 waited and not released the valsartan in
11 the market that you could have actually
12 saved people's lives?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: I don't
16 think that there's been any
17 conclusions that even if people
18 ingested product with these
19 impurities that it has cost people
20 their lives. That's a lot of
21 speculation.
22 BY MS. PAPANTONIO:
23 Q. Well, the jury is actually
24 going to be able to see plenty of examples

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1 of that when we show this in trial. But do
2 you understand that had you not released
3 this product from the market that you could
4 have saved a person from taking valsartan
5 that was contaminated with NDMA that was
6 400 times the FDA threshold?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: Again, we
10 had no indication the NDMA was
11 present.
12 BY MS. PAPANTONIO:
13 Q. Okay. 1171. We're going to LP
14 1171. Okay. Ms. Chitty, the FDA --
15 Torrent released valsartan back onto the
16 market on July 18; isn't that right?
17 A. I don't recall the exact date,
18 but it was something close to that.
19 Q. Okay. And what we know now is
20 that the product that Torrent released was
21 contaminated with NDMA, right?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: I would

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1 have to look at the specific
2 batches, because I believe there
3 were some batches that were
4 containing that impurity and some
5 that were not.
6 - - - - -
7 (Notification Bates
8 TORRENT-MDL2875-00131255 marked
9 Torrent Exhibit 92 for
10 identification.)
11 - - - - -
12 BY MS. PAPANTONIO:
13 Q. Okay. And on August 3rd, this
14 is now about 45 days after you had gotten
15 the initial notice from ZHP, right, you're
16 getting another notification from ZHP?
17 A. This is dated August 3, yes,
18 and it's roughly a month and a half after
19 their initial communication.
20 Q. For a month and a half, Torrent
21 believed that what ZHP was telling them was
22 accurate information?
23 MS. NAGLE: Objection,
24 form. And, counsel, can we just

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1 get an exhibit number, please?
2 MS. PAPANTONIO: Ninety-
3 two, sorry, Torrent 92.
4 MS. NAGLE: Thank you.
5 THE WITNESS: So leading
6 up to this communication, we had
7 not been aware that there was any
8 trace amounts of NDMA in the old
9 process API.
10 BY MS. PAPANTONIO:
11 Q. And let's take a look at what
12 this communication is actually telling you,
13 right. The title says valsartan API and
14 then NDMA, right?
15 A. Yes.
16 Q. And then ZHP tells you that
17 after further assessment "trace amounts of
18 NDMA is detected in the valsartan API
19 manufactured with old process," right?
20 A. That is what that says.
21 Q. Was that a shock to you?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: It was new

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1 information that we had not seen.
2 BY MS. PAPANTONIO:
3 Q. Right, because for a month and
4 a half, you had relied on ZHP to give you
5 accurate information?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: We were
9 relying on the information from ZHP
10 as being accurate.
11 BY MS. PAPANTONIO:
12 Q. For this entire time, a month
13 and a half, you were conveying to the FDA
14 and customers that Torrent valsartan was
15 safe?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: Based on
19 the information we had in hand at
20 the time of those communications,
21 we were communicating that we did
22 not think the discussed impurity
23 was in our batches.
24

<p style="text-align: right;">Page 290</p> <p>1 BY MS. PAPANTONIO: 2 Q. For that month and a half, 3 Torrent continued to sell valsartan, right? 4 A. I don't know for the entire 5 month and a half. At some point, we had 6 product under quarantine and then it was 7 subsequently released. 8 Q. And we know it was released 9 around the 18th, so between the 18th and 10 now the 3rd, contaminated valsartan is on 11 the market, right? 12 MS. NAGLE: Objection, 13 form. 14 THE WITNESS: And again, 15 I don't know if those batches that 16 were quarantined were batches that 17 were impacted by this impurity. 18 BY MS. PAPANTONIO: 19 Q. Okay. August 3, you learned 20 NDMA is in Torrent's product. On August 3, 21 does Torrent pull that product off the 22 market? 23 MS. NAGLE: Objection, 24 form.</p>	<p style="text-align: right;">Page 292</p> <p>1 today is that trace amounts equates to 400 2 times the FDA threshold? 3 MS. NAGLE: Objection, 4 form. 5 THE WITNESS: No, my 6 point was we can't define what 7 trace amounts are. 8 BY MS. PAPANTONIO: 9 Q. Right. So at this point on 10 August 3, after Torrent learns that its 11 product is contaminated with NDMA, Torrent 12 responds by saying, it's no big deal, it's 13 just trace amounts, right? That's what 14 you're telling us? 15 MS. NAGLE: Objection, 16 form. 17 THE WITNESS: I'm 18 telling you that we have to have 19 quantifiable numbers, because there 20 are situations where certain 21 amounts of impurities, even 22 genotoxic or carcinogenic 23 impurities, are allowed in drug 24 products by regulation. So there's</p>
<p style="text-align: right;">Page 291</p> <p>1 THE WITNESS: I would 2 have to review some emails. I 3 don't remember exactly what we did 4 on August 3, but one of the 5 important points in this is that 6 they're referring to trace amounts, 7 so at this point, we don't really 8 know how much is there and if it 9 might be below allowable levels. 10 BY MS. PAPANTONIO: 11 Q. Ms. Chitty, but now you know 12 that trace amounts actually means 400 times 13 the FDA threshold limit for NDMA in a 14 product, right? 15 MS. NAGLE: Objection, 16 form. 17 THE WITNESS: There were 18 data presented at some point that I 19 am aware of now, yes, that show 20 some of those API batches that 21 Torrent had utilized were over the 22 allowable limits. 23 BY MS. PAPANTONIO: 24 Q. And what you're telling us</p>	<p style="text-align: right;">Page 293</p> <p>1 nothing in this letter that tells 2 us, you know, definitively how much 3 a trace amount means. 4 BY MS. PAPANTONIO: 5 Q. And on August 3, did Torrent 6 immediately test this product to determine 7 what trace amount means? 8 MS. NAGLE: Objection. 9 Form and foundation. 10 THE WITNESS: On 11 August 3, I would have to go back 12 to, again, see if we had a method 13 at this time that was able to 14 adequately and accurately detect 15 the small amounts of the potential 16 impurities. 17 BY MS. PAPANTONIO: 18 Q. We're going to talk about that 19 method in a few minutes, but as far as 20 you're aware, on August 3, Torrent did not 21 have a way to test this product to 22 determine whether or not there were trace 23 amounts? 24 MS. NAGLE: Objection,</p>

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1 form.
 2 THE WITNESS: I don't
 3 recall. Again, there's a lot of,
 4 you know, kind of information
 5 coming from different places as of
 6 August 3. I don't recall where we
 7 were in developing or obtaining
 8 details of the method.
 9 BY MS. PAPANTONIO:
 10 Q. Do you recall Torrent
 11 immediately sending samples to independent
 12 labs for them to verify the NDMA in
 13 Torrent's valsartan?
 14 MS. NAGLE: Objection.
 15 Form and foundation.
 16 THE WITNESS: That's not
 17 something I really would have been
 18 involved in.
 19 BY MS. PAPANTONIO:
 20 Q. Do you recall Torrent reaching
 21 out to the other manufacturers who had
 22 already tested the NDMA to ask for help on
 23 how to test Torrent's product?
 24 MS. NAGLE: Objection.

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1 Form and foundation.
 2 THE WITNESS: Again,
 3 that's not something I was aware of
 4 or necessarily would have been
 5 involved in.
 6 BY MS. PAPANTONIO:
 7 Q. So we're at August 3, Torrent
 8 learns that there's NDMA in their product,
 9 and they don't do anything?
 10 MS. NAGLE: Objection,
 11 form.
 12 THE WITNESS: So this
 13 notification from August 3 does not
 14 specify which batches of old
 15 process product it was detected in.
 16 So, again, at this point, we don't
 17 really have any information on the
 18 specifics and we should have taken
 19 the action stated here to go ahead
 20 and quarantine product until more
 21 information is available.
 22 BY MS. PAPANTONIO:
 23 Q. So you believe that at this
 24 point Torrent should have immediately

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1 quarantined their product?
 2 A. We would have likely
 3 quarantined the API as noted here.
 4 Q. Not likely, do you believe that
 5 Torrent should have quarantined their
 6 product?
 7 A. In my personal opinion, we
 8 should have quarantined the API and
 9 potential product.
 10 Q. In your experience, based as a
 11 regulatory consultant, do you think that
 12 Torrent should have recalled their product
 13 on August 3?
 14 A. As of August 3, we still don't
 15 have enough details to know, again, which
 16 batches might contain the impurity nor at
 17 what levels, because there are allowable
 18 levels associated with certain impurities,
 19 so we have -- we have no data at this point
 20 to know which batches to recall and which
 21 batches might be impacted.
 22 Q. But we do know that on
 23 August 3, Torrent has customers that are
 24 still taking Torrent's valsartan, right?

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1 MS. NAGLE: Objection.
 2 Form and foundation.
 3 THE WITNESS: It is
 4 likely consumers were still taking
 5 Torrent product on August 3.
 6 BY MS. PAPANTONIO:
 7 Q. Okay. I want to talk about
 8 this from the consumer perspective, because
 9 you know, what we talked about is that the
 10 FDA recalled three manufacturers' valsartan
 11 on July 13. Do you remember that?
 12 A. Yeah, I believe it was the
 13 13th of July.
 14 Q. And you understand that that
 15 when a product is recalled, it is removed
 16 from the shelves, people can no longer buy
 17 it?
 18 A. It depends on what level of
 19 recall it is. But product is removed from
 20 the markets. It doesn't necessarily mean
 21 that consumers aren't still buying it or
 22 using it.
 23 Q. All right. So the products
 24 that were recalled on July 13 were no

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1 longer available to valsartan users?
 2 MS. NAGLE: Form and
 3 foundation.
 4 THE WITNESS: Again, it
 5 depends on the level of recall. So
 6 I'm not 100 percent sure of the
 7 details of those recalls from that
 8 time.
 9 BY MS. PAPANTONIO:
 10 Q. Well, you know just from your
 11 experience with Torrent that when Torrent
 12 recalled its product, it actually asked all
 13 of the customers to send the product back
 14 to Torrent, right?
 15 A. That was part of the
 16 instructions related to the Torrent
 17 product. The communications also very
 18 clearly told patients to not stop taking
 19 product until they had spoken with their
 20 doctors.
 21 Q. Exactly. You don't -- so
 22 people who rely on valsartan as a blood
 23 pressure medication that had that
 24 medication recalled would have to find an

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1 alternative medication after the July 13
 2 recall, right?
 3 MS. NAGLE: Objection.
 4 Form and foundation.
 5 THE WITNESS: If you
 6 were taking a recalled product, a
 7 product that was recalled from the
 8 July 13 recall, yes, your doctor
 9 would have recommended a different
 10 product for you, most likely.
 11 BY MS. PAPANTONIO:
 12 Q. And after the July 13 recall,
 13 Torrent was advertising their product as
 14 being safe?
 15 MS. NAGLE: Objection.
 16 Form and foundation.
 17 THE WITNESS: We do no
 18 advertising in the generic
 19 business, so no, we were not
 20 advertising our product as safe.
 21 BY MS. PAPANTONIO:
 22 Q. Well, let me rephrase the
 23 question. If one of these customers who
 24 relied on recalled valsartan had called

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1 Torrent up and asked you if your product
 2 was recalled, you would have told them no?
 3 MS. NAGLE: Objection,
 4 form.
 5 THE WITNESS: That's
 6 correct, at that time, our product
 7 was not recalled.
 8 BY MS. PAPANTONIO:
 9 Q. You would have told that
 10 customer that Torrent's product is safe to
 11 use and not a part of the recall?
 12 MS. NAGLE: Objection,
 13 form.
 14 THE WITNESS: We would
 15 have confirmed it was not part of
 16 the recall, yes.
 17 BY MS. PAPANTONIO:
 18 Q. Are you aware that customers
 19 actually switched from a recalled brand
 20 valsartan to Torrent's brand valsartan
 21 because they believed the product had no
 22 NDMA in it?
 23 MS. NAGLE: Objection,
 24 form.

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1 THE WITNESS: I'm not
 2 personally aware of that, no.
 3 BY MS. PAPANTONIO:
 4 Q. Are you aware that valsartan
 5 users switched to Torrent valsartan because
 6 they believed that Torrent valsartan was
 7 safe?
 8 MS. NAGLE: Objection,
 9 form.
 10 THE WITNESS: No, I'm
 11 not personally aware of that.
 12 BY MS. PAPANTONIO:
 13 Q. Are you aware that the
 14 customers who relied on recalled valsartan
 15 that later switched to Torrent valsartan
 16 could have been taking 400 times the level
 17 of NDMA in Torrent's valsartan each day?
 18 MS. NAGLE: Objection,
 19 form.
 20 THE WITNESS: Again,
 21 there weren't testing data -- there
 22 weren't results indicating that
 23 impurity at that time, so no, I'm
 24 not personally aware of consumers

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1 taking specific products.
2 BY MS. PAPANTONIO:
3 Q. Are you aware of any
4 conversation that happened after the
5 July 13 recall of Torrent's sales
6 increasing because more customers were
7 switching to Torrent valsartan?
8 MS. NAGLE: Objection,
9 form.
10 THE WITNESS: Not that I
11 recall.
12 BY MS. PAPANTONIO:
13 Q. Are you aware of any increase
14 in demands for Torrent's valsartan product?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: Not that I
18 can recall.
19 BY MS. PAPANTONIO:
20 Q. Do you understand though that
21 valsartan customers who relied on the
22 recalled product could actually have been
23 taking a more dangerous product had they
24 switched to Torrent?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: No, I am
4 not aware of what you mentioned.
5 BY MS. PAPANTONIO:
6 Q. Okay. So back to this August 3
7 notification, are you aware that Torrent
8 didn't actually recall its valsartan until
9 August 22?
10 A. I don't recall the exact date,
11 but I remember it was not recalled in
12 relation to this August 3 notification,
13 again, because it's not specific in its
14 details to give us enough information to
15 really make an informed decision.
16 Q. And on August 3, Torrent didn't
17 immediately seek out information to
18 determine whether or not its valsartan was
19 safe?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: I can't
23 speak personally for what all of
24 Torrent was doing on August 3 to

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1 seek out information, sorry.
2 BY MS. PAPANTONIO:
3 Q. But you can speak for yourself
4 and at any point did you contact Torrent
5 quality in India and demand that they test
6 this drug to determine if NDMA is present?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: I'm not
10 sure what communications I sent
11 specifically on August 3. We had
12 already been discussing the need
13 for additional confirmatory testing
14 and method development.
15 BY MS. PAPANTONIO:
16 Q. So after this recall, things
17 were just business as usual or after this
18 notification, things at Torrent were just
19 business as usual?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: No, this
23 was, again, a new piece of
24 information. Again, I just don't

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1 specifically recall what I did
2 three years ago on this day and I
3 can't really speak to all of the
4 other activities that might have
5 been going on at that time.
6 BY MS. PAPANTONIO:
7 Q. Okay. Let's look at LP 682.
8 This is marked as Torrent 12. Okay. We're
9 going to go to the second page. We can see
10 we're looking at another email sent by you,
11 Ms. Chitty. And this looks like it's to a
12 couple of people. So Jaiswal is in
13 quality, correct?
14 A. I can't remember what he was
15 doing. He somehow was associated with the
16 plant.
17 Q. What about Vora?
18 A. I don't remember specifically
19 what Hardik was responsible for.
20 Q. Okay. We can see that this
21 email was sent by you on August 11, 2018,
22 right, that is one week after you got
23 notification from ZHP?
24 A. Yes.

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1 Q. And if we look at the email,
2 you tell us that the FDA is requesting
3 information on a specific batch. The
4 C50691553. Do you see that?
5 A. Yes.
6 Q. That C number is an API code
7 from ZHP, right?
8 A. That is an API batch number,
9 yes.
10 Q. And you tell us that the FDA
11 believes that there might be NDMA in this
12 batch, right? That's on the second --
13 there we go.
14 A. Correct. That is in the
15 message.
16 Q. So, again, the FDA is telling
17 you that your product is not safe, Torrent
18 is not actually testing the product
19 themselves, correct?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: I mean, I
23 think that the question here seems
24 to be whether we've received that

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1 batch or not.
2 BY MS. PAPANTONIO:
3 Q. Okay. And so at this point, a
4 full week after you got notification from
5 ZHP that NDMA was an old process, Torrent
6 is still selling the drug valsartan?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: I am not
10 certain what status we are here in
11 terms of quarantining product and
12 things like that, so I can't say if
13 we're still selling at this point.
14 BY MS. PAPANTONIO:
15 Q. Okay. But what you do conclude
16 is you say "Also, have we been able to
17 develop or transfer a method to test for
18 NDMA?" Do you see that?
19 A. Yes.
20 Q. This is one week after you
21 learn that NDMA is in Torrent's product and
22 you still cannot test your product to
23 determine whether or not it's safe; is that
24 accurate?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: As of the
4 11th, it seems that we still don't
5 have a method that's suitable for
6 accurately testing for the
7 impurity.
8 BY MS. PAPANTONIO:
9 Q. This is now two months after
10 you got the initial notice of a genotoxic
11 impurity?
12 A. Not quite two months.
13 Q. Right. Six days short, a
14 couple of days short. We can agree it's a
15 long time, Ms. Chitty, right?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: It's
19 slightly under two months.
20 BY MS. PAPANTONIO:
21 Q. Okay. And so two months after
22 you learn that there's a potentially
23 dangerous carcinogen in valsartan, you
24 still cannot test the valsartan drug to

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1 make sure that it is safe?
2 MS. NAGLE: Objection,
3 form.
4 THE WITNESS: I mean,
5 again, I think the notification we
6 received in June, we did not
7 believe applied to the product we
8 were using, the API route of
9 synthesis that we were using at the
10 time, and we continued to work on a
11 method to try to be able to test
12 accurately and understand the
13 situation better.
14 BY MS. PAPANTONIO:
15 Q. And now, a full week after, you
16 get notification that your drug is actually
17 affected by NDMA, you still can't test to
18 determine whether or not what ZHP is saying
19 is correct?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: Again,
23 this is a week after we're given
24 data that's difficult to quantify,

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1 because we don't know the levels.
2 We don't know the batches that may
3 be impacted.
4 BY MS. PAPANTONIO:
5 Q. Ms. Chitty, would you agree
6 that this is a big deal that NDMA is in
7 your product?
8 MS. NAGLE: Objection,
9 form.
10 THE WITNESS: It is
11 definitely important.
12 BY MS. PAPANTONIO:
13 Q. Right. So you should be
14 finding a method as soon as possible,
15 right?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: And to my
19 knowledge, the team was working on
20 developing that method or obtaining
21 a method as soon as they could.
22 BY MS. PAPANTONIO:
23 Q. And on August 11, you still
24 don't have it?

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1 A. That appears to be the case by
2 this email, yes.
3 BY MS. PAPANTONIO:
4 Q. Okay. And then you go on to
5 say, "If this batch creates NDMA it creates
6 a potential problem." What is that
7 problem?
8 A. It raises the question of NDMA
9 being present in the old process route of
10 synthesis, I believe, what I meant by that
11 statement.
12 Q. Well, it's more than just that,
13 it's a potential problem because your
14 consumers are potentially taking the
15 carcinogenic pill, right? Would you agree
16 with that?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: Consumers
20 are potentially taking a product
21 with an impurity at a level we
22 don't know and, likely, I think, at
23 this point, I'm not sure if FDA had
24 set standard limits that were

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1 acceptable at this point yet.
2 BY MS. PAPANTONIO:
3 Q. Well, we know they had set
4 standards limits because those limits were
5 imposed in the initial recall on July 13?
6 MS. NAGLE: Objection.
7 Form and foundation.
8 THE WITNESS: Okay.
9 Yeah, I just -- I don't remember
10 the sequence of when those limits
11 came out.
12 BY MS. PAPANTONIO:
13 Q. Ms. Chitty, will you agree that
14 this is more than a potential problem,
15 because consumers take this drug on a daily
16 basis?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: I think
20 the frequency of a consumer taking
21 a product doesn't really impact our
22 decision, you know, if it was
23 important, and we were certainly
24 concerned and actively trying to

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1 gather information on this to make
2 sure we were acting appropriately.
3 BY MS. PAPANTONIO:
4 Q. So if a consumer had taken
5 valsartan with NDMA over 400 times the FDA
6 threshold every single day for four years,
7 that wouldn't be a potential problem for
8 Torrent?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: You know,
12 I can't kind of evaluate the
13 potential impact of that type of
14 situation. Again, I'm not a
15 toxicologist. I'm not a doctor.
16 And the limits were just starting
17 to come out from regulators as we
18 were working through all of these
19 details.
20 BY MS. PAPANTONIO:
21 Q. Right. You go on to say "If
22 this batch creates NDMA it creates a
23 potential problem unless we can prove our
24 batches do not contain NDMA." So at this

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1 point, you're still trying to prove ZHP
2 wrong, right?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: I'm not
6 sure that we're trying to prove ZHP
7 wrong, no. I think we're trying to
8 gather our own additional data to
9 confirm the data that we have.
10 BY MS. PAPANTONIO:
11 Q. Right. And at this point, you
12 still cannot test the batch to determine
13 whether your batches do or do not contain
14 NDMA?
15 A. By the context of this email,
16 yeah, it seems that there's still not an
17 appropriate method of testing of the
18 impurity.
19 Q. Okay, let's look at LP 1063.
20 Okay. Looking at this email, this is
21 another email -- oh, Exhibit No. 25, excuse
22 me, Torrent 25. Okay. Let's look at the
23 second email here or the third email here.
24 We see that it's sent by you. And then the

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1 subject is "FDA meeting regarding
2 valsartan" and it says urgent, right? And
3 it's urgent because Torrent's product
4 potentially contains a carcinogen, right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: Sorry, I'm
8 just trying to look at the details.
9 Yeah, it is urgent because FDA is
10 at this point telling us that
11 they've detected NDMA in certain
12 samples that we provided to them.
13 BY MS. PAPANTONIO:
14 Q. Right, so the FDA has a test,
15 but Torrent still does not have a test to
16 determine whether or not its product is
17 safe?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: I'm not
21 sure, but I think on this date, we
22 still did not have an appropriate
23 method.
24

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1 BY MS. PAPANTONIO:
2 Q. And this date is August 16?
3 A. Yes.
4 Q. That is now 13 days, almost two
5 weeks after you got notice from ZHP that
6 Torrent's valsartan contained NDMA?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: It is
10 approximately two weeks after the
11 notification that said that ZHP had
12 detected the impurity in some
13 batches. Again, we did not know
14 which batches nor whether those
15 batches specifically were used in
16 Torrent product at that time.
17 BY MS. PAPANTONIO:
18 Q. And at this point, Torrent had
19 still not recalled the valsartan product?
20 A. I believe not. I think you
21 said that date was the 22nd or the 23rd of
22 August.
23 Q. Despite knowing that Torrent's
24 valsartan was contaminated with NDMA.

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: Again, on
4 this date, we did not have
5 conclusive information that the
6 batches that Torrent had used were
7 impacted.
8 BY MS. PAPANTONIO:
9 Q. And you don't have conclusive
10 information, because you don't have the
11 ability to test; isn't that correct?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: To
15 accurately test at this point,
16 correct.
17 BY MS. PAPANTONIO:
18 Q. So, Ms. Chitty, let me ask you,
19 at this point, since you can't test the
20 product, why not just recall it?
21 MS. NAGLE: Objection.
22 Form and foundation.
23 THE WITNESS: In
24 general, you don't recall something

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1 without information. You know, I
 2 know that at some point, there were
 3 also market concerns regarding
 4 shortages. There's just a lot of
 5 consequences of taking a product
 6 off the market for no reason. So
 7 you don't make those decisions
 8 until you have some firm data in
 9 hand to support them.
 10 BY MS. PAPANTONIO:
 11 Q. Ms. Chitty, would you also
 12 agree with me that there's a lot of
 13 consequences to taking valsartan
 14 contaminated with a carcinogen?
 15 MS. NAGLE: Objection,
 16 form.
 17 THE WITNESS: Again, I'm
 18 not a toxicologist or doctor, so
 19 I'm really not qualified to make a
 20 conclusion.
 21 BY MS. PAPANTONIO:
 22 Q. Would you agree with me that
 23 there are a lot of consequences to taking
 24 valsartan that is contaminated with NDMA at

Page 319

1 levels 400 times over the FDA threshold?
 2 MS. NAGLE: Objection,
 3 form.
 4 THE WITNESS: Again, I'm
 5 not qualified to make that
 6 decision.
 7 BY MS. PAPANTONIO:
 8 Q. Do you understand that one of
 9 the consequences of ingesting NDMA is
 10 cancer?
 11 MS. NAGLE: Objection,
 12 form.
 13 THE WITNESS: Again, I'm
 14 not specifically aware of that
 15 information.
 16 BY MS. PAPANTONIO:
 17 Q. Do you understand, are you
 18 aware of the fact that one of the
 19 consequences of cancer is actually death?
 20 MS. NAGLE: Objection,
 21 form. And, Counsel, the tone is
 22 getting a little bit much.
 23 MS. PAPANTONIO: You can
 24 answer the question.

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1 THE WITNESS: One of the
 2 potential consequences of cancer
 3 can be death, yes.
 4 BY MS. PAPANTONIO:
 5 Q. So the consequences Torrent is
 6 dealing with is the loss of income, right?
 7 MS. NAGLE: Objection,
 8 form.
 9 THE WITNESS: No. As
 10 I've mentioned, there's always
 11 financial considerations in what
 12 we're doing, but those are not the
 13 primary drivers for quality-based
 14 decisions.
 15 BY MS. PAPANTONIO:
 16 Q. But you understand that one of
 17 the consequences for your customers, for
 18 people taking this valsartan, could
 19 actually be death?
 20 MS. NAGLE: Objection,
 21 form.
 22 THE WITNESS: No.
 23 Again, I'm not trained in the
 24 proper area to be able to conclude

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1 that that is a likely or probable
 2 scenario.
 3 BY MS. PAPANTONIO:
 4 Q. But you understand that when
 5 Torrent was evaluating the consequences of
 6 whether or not they keep their drug on the
 7 market, they chose to continue to sell the
 8 drug?
 9 MS. NAGLE: Objection,
 10 form.
 11 THE WITNESS: Torrent
 12 made data-based decisions and as
 13 soon as we were aware of NDMA
 14 contamination in batches, we took
 15 action to recall those.
 16 BY MS. PAPANTONIO:
 17 Q. And the longer it takes Torrent
 18 to develop a test method to test NDMA, the
 19 longer valsartan stays on the market; would
 20 you agree with that statement?
 21 MS. NAGLE: Objection.
 22 Form and foundation.
 23 THE WITNESS: I can't
 24 really, I mean, connect those two

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1 things directly.
2 BY MS. PAPANTONIO:
3 Q. I think you can, Ms. Chitty.
4 Let's break it down. As more time goes by,
5 more people continue to take valsartan by
6 Torrent?
7 MS. NAGLE: Objection.
8 Form and foundation.
9 THE WITNESS: As -- I
10 mean, I don't think I can answer
11 that question. I mean,
12 knowledgeably, there are people in
13 the market taking our product. I
14 can't really quantify in a very
15 specific way.
16 BY MS. PAPANTONIO:
17 Q. Okay. And the longer it takes
18 Torrent to develop a testing method, the
19 longer Torrent valsartan stays on the
20 market?
21 MS. NAGLE: Objection,
22 form.
23 THE WITNESS: The method
24 was being developed, you know, I

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1 think as quickly -- as quickly as
2 it could and we were also taking
3 information from other sources. So
4 the Torrent results from potential
5 testing were not the only piece of
6 information that was driving, you
7 know, decision-making at that
8 point.
9 BY MS. PAPANTONIO:
10 Q. Okay. Let's look on what
11 you're telling your colleagues on this
12 second page of your email that you sent.
13 We already looked at this earlier today,
14 but we're putting it in context to this
15 timeline. Okay. Let's blow that up.
16 You're telling the quality department in
17 India, we really need a method to evaluate
18 these products ourselves, right? Do you
19 agree that two weeks after Torrent learns
20 its product is unsafe that you really need
21 a method to test the product? Is that an
22 accurate statement?
23 MS. NAGLE: Objection,
24 form.

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1 THE WITNESS: Outside of
2 the timing context, you know, I had
3 always been a strong proponent of
4 getting this method together so
5 that we have additional data to
6 make decisions off of.
7 BY MS. PAPANTONIO:
8 Q. I mean, absolutely, Ms. Chitty,
9 because you truly understand that there are
10 patients at risk at this time, right?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: I mean,
14 based at this point in time, we
15 were not in possession of data to
16 suggest that our batches were
17 directly impacted by this impurity
18 other than, I think, what was
19 mentioned originally from FDA in
20 this email chain.
21 BY MS. PAPANTONIO:
22 Q. And you're emphasizing to the
23 people who are responsible for getting that
24 data, you're emphasizing for the third time

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1 now, we need this data, we've got to have
2 it. That's what you're telling Torrent
3 India, right?
4 MS. NAGLE: Objection,
5 form.
6 THE WITNESS: I'm not
7 sure if I categorize it as
8 emphasizing, but I'm stating my
9 opinion again.
10 BY MS. PAPANTONIO:
11 Q. Well, just in the grand scheme
12 of things, this is now the third time that
13 you have asked Torrent India to give you
14 the data you need?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: Was that a
18 question, I'm sorry?
19 BY MS. PAPANTONIO:
20 Q. Right. So you've asked Torrent
21 India to give you the data you need so you
22 can communicate that information to the
23 FDA?
24 A. I had asked India for

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1 additional data, yes.
 2 Q. Right. Because then you follow
 3 that statement by saying or else we'll have
 4 no evidence to argue with them if they're
 5 telling us that they are finding impurities
 6 in our testing, right?
 7 A. That is what the email says,
 8 yes.
 9 Q. You're saying there is no way
 10 to argue with the FDA about impurity
 11 levels?
 12 MS. NAGLE: Objection,
 13 form.
 14 THE WITNESS: I think
 15 what I'm trying to say here is that
 16 we would have no additional data of
 17 our own to, you know, bring to FDA.
 18 BY MS. PAPANTONIO:
 19 Q. Right. You would have no
 20 additional data to tell the FDA that their
 21 tests are inaccurate?
 22 A. Correct, that is the point of
 23 this couple sentences.
 24 Q. You would have no data to tell

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1 the FDA that Torrent should actually keep
 2 their drug on the market?
 3 MS. NAGLE: Objection,
 4 form.
 5 THE WITNESS: Again, was
 6 that a question or a statement, I'm
 7 sorry?
 8 BY MS. PAPANTONIO:
 9 Q. That was a question.
 10 A. Could you repeat --
 11 Q. That's why you need the data,
 12 to convince the FDA to keep Torrent's
 13 product on the market?
 14 MS. NAGLE: Objection,
 15 form.
 16 THE WITNESS: Again,
 17 that didn't seem like a question to
 18 me, I'm sorry.
 19 BY MS. PAPANTONIO:
 20 Q. Well, would you agree with that
 21 statement?
 22 A. Can you repeat that statement?
 23 Q. The reason Torrent needs data
 24 is so that they can argue with the FDA and

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1 ask the FDA to keep Torrent's product on
 2 the market?
 3 MS. NAGLE: Same
 4 objection.
 5 THE WITNESS: I think
 6 it's mischaracterization to say
 7 that our intent was to keep the
 8 product on the market. I think my
 9 intent is we want our own data to
 10 understand our specific product
 11 situation, because as I mentioned
 12 before, methods are very specific
 13 to the composition of tablets, for
 14 instance. And so since we don't
 15 know a lot about the FDA method,
 16 we're not sure how accurately it
 17 might work on our specific
 18 products, for instance, so --
 19 BY MS. PAPANTONIO:
 20 Q. Well, Ms. Chitty, in your
 21 words, you would have no evidence to argue
 22 with them. Do you see that?
 23 A. Correct, that's what it says.
 24 Q. In other words, you would just

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1 have to take the information that the FDA
 2 is giving without argument?
 3 MS. NAGLE: Objection,
 4 form.
 5 THE WITNESS: We would
 6 have no kind of additional data for
 7 discussion, correct, if we don't
 8 have our own method at the time.
 9 BY MS. PAPANTONIO:
 10 Q. Okay. LP 1033. Do you
 11 recognize this email?
 12 A. I don't remember it
 13 specifically, but obviously, this was
 14 minutes of a follow-up call with FDA.
 15 Q. Right. So this is email was
 16 sent on the same day of that email we were
 17 just looking at where you were saying we
 18 had to test the product, right?
 19 MS. NAGLE: Sorry, just
 20 real quickly, Counsel, can you just
 21 give us the exhibit number again
 22 before the --
 23 MS. PAPANTONIO: Yup,
 24 Torrent 26. Sorry.

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1 MS. NAGLE: Thank you so
2 much.
3 THE WITNESS: Yeah, I
4 believe this is the same day.
5 BY MS. PAPANTONIO:
6 Q. And the subject of this is
7 "WebEx meeting with the FDA about valsartan
8 products." Do you recall that meeting?
9 A. Yes, I recall that meeting.
10 Q. Okay. We can see this email
11 was sent to you by Jocelyn Rivera, right?
12 Does she work for you?
13 A. Yes, she did at the time.
14 Q. Okay. And what we can see is
15 that the FDA is calling a meeting with
16 Torrent, right?
17 A. Correct.
18 Q. And then the attendees from
19 Torrent are you, Dawn Chitty, and Jocelyn
20 Rivera, right?
21 A. Correct.
22 Q. And then from the FDA, there
23 are 18 attendees, right?
24 A. I'll take your word that that's

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1 about 18 attendees there in that list.
2 Q. That's a lot of people -- this
3 is, obviously, pretty important to the FDA,
4 right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: It is hard
8 to judge importance or significance
9 from the number of people that
10 attend an FDA meeting just because
11 of the way they're structured,
12 there's lots of divisions, lots of
13 areas, so I don't know if I've ever
14 had an FDA meeting with less than,
15 you know, ten or 12 FDA attendees
16 in participation, so.
17 BY MS. PAPANTONIO:
18 Q. Okay. Well, Torrent only sent
19 two people, right, you and Ms. Rivera? So
20 who is Ms. Rivera?
21 A. Jocelyn was someone that worked
22 for me in the regulatory affairs team in
23 the U.S.
24 Q. Is Ms. Rivera someone that you

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1 trusted?
2 MS. NAGLE: Objection,
3 form.
4 THE WITNESS: She was a
5 good employee. Certainly someone I
6 didn't not trust.
7 BY MS. PAPANTONIO:
8 Q. So did you often rely on
9 Ms. Rivera?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: Again, she
13 was one of the people who worked
14 for me, so yes, she was someone who
15 would participate in various
16 activities.
17 BY MS. PAPANTONIO:
18 Q. Did she communicate with the
19 FDA often?
20 A. Typically, I was the main
21 person communicating with FDA.
22 Q. But overall, do you think she
23 was a pretty good employee?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: Yes.
3 BY MS. PAPANTONIO:
4 Q. Now, is Ms. Rivera someone who
5 is ultimately responsible for the quality
6 of Torrent's valsartan?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: No.
10 Again, she worked within my U.S.
11 regulatory team, not necessarily
12 within quality assurance, for
13 instance.
14 BY MS. PAPANTONIO:
15 Q. Okay. So let's look at the
16 purpose of the meeting. It says the
17 purpose of the meeting is "to share
18 analytical information from the FDA."
19 Right, because we know that at this point,
20 August 18, Torrent still does not know how
21 to test its own products for NDMA; is that
22 correct?
23 MS. NAGLE: Objection,
24 form.

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1 THE WITNESS: At this
2 point, this meeting is, as
3 mentioned here, they're going to
4 share information with us regarding
5 the testing that they had done.
6 BY MS. PAPANTONIO:
7 Q. Right. And they're sharing
8 that information with Torrent, because
9 Torrent doesn't have that information
10 themselves at this point?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: They're
14 sharing that information with
15 Torrent because they have that
16 information to share.
17 BY MS. PAPANTONIO:
18 Q. And on this date, like you said
19 in the previous email, you have no evidence
20 to argue with the FDA about the NDMA levels
21 in Torrent's valsartan at this meeting?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: As of this

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1 date, it seemed that we did not
2 have the method adequately
3 developed to accurately test for
4 the impurity.
5 BY MS. PAPANTONIO:
6 Q. So at this date on August 28 --
7 move to strike that, actually. So Torrent
8 has been selling valsartan since around
9 2010, right?
10 MS. NAGLE: Objection.
11 Form and foundation.
12 THE WITNESS: I don't
13 recall when it was approved.
14 BY MS. PAPANTONIO:
15 Q. Does that sound about right?
16 A. I don't think so. I think
17 that's too early. But again, I don't
18 recall specifically.
19 Q. You have been selling it, let's
20 say, at least five to seven years at this
21 point?
22 MS. NAGLE: Objection.
23 Form and foundation.
24 THE WITNESS: I'm not

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1 sure. You guys should have
2 approval letters. I mean, that's
3 publicly available information, so.
4 BY MS. PAPANTONIO:
5 Q. Okay. But you do sell
6 valsartan to multiple countries, right?
7 MS. NAGLE: Objection.
8 Form and foundation.
9 THE WITNESS: I was
10 primarily responsible for the U.S.,
11 so I don't know the specifics, but
12 yes, I believe it was being sold in
13 other countries besides the U.S.
14 also.
15 BY MS. PAPANTONIO:
16 Q. And you sell tens of millions
17 of pills each year?
18 MS. NAGLE: Objection.
19 Form and foundation.
20 THE WITNESS: I can't
21 really comment on exact quantities.
22 That wasn't kind of my area, so.
23 BY MS. PAPANTONIO:
24 Q. Right, but we know at this

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1 date, August of 2018, you had been selling
2 valsartan -- Torrent has been selling
3 valsartan for years, right?
4 MS. NAGLE: Objection,
5 form.
6 THE WITNESS: Again, I
7 don't have the exact date, but we
8 had been selling it for some bit of
9 time since it had been approved.
10 BY MS. PAPANTONIO:
11 Q. Torrent had been manufacturing
12 that finished dose again for a long period
13 of years?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: I can't
17 really define what you mean by long
18 period of years, so, without a
19 date.
20 BY MS. PAPANTONIO:
21 Q. Okay. Now, Ms. Chitty, you
22 understand that it's not the FDA's job to
23 find problems with Torrent's drugs, right?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: That is
3 potentially not their primary job.
4 It is something that they do even
5 under routine situations of testing
6 product to confirm compliance.
7 BY MS. PAPANTONIO:
8 Q. As a finished dose
9 manufacturer, you understand that it is
10 your job to test your own product to
11 determine whether or not it meets quality
12 standards?
13 MS. NAGLE: Objection.
14 Form and foundation.
15 THE WITNESS: Correct.
16 It is our job to test our product
17 before it's released.
18 BY MS. PAPANTONIO:
19 Q. So this is a meeting with the
20 FDA where they have tested your drug for
21 quality and you have not tested the drug?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: No, that's

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1 not an accurate statement. We had
2 tested the product. We did not
3 have the ability at the time to
4 test specifically for these small
5 quantities of this impurity.
6 BY MS. PAPANTONIO:
7 Q. And the FDA tells Torrent that
8 present -- on this email it says present at
9 high sides with values ranging between 37
10 ppm to 39 ppm NDMA was found?
11 A. That's what's noted there in
12 that message, yes.
13 Q. Right. And this is actually on
14 the low end of what we have seen today,
15 this 37 ppm?
16 MS. NAGLE: Objection,
17 form.
18 MS. PAPANTONIO: Right?
19 THE WITNESS: I'm not
20 sure what you're referring to when
21 you say what we've seen today.
22 There's been a lot of data from
23 various sources.
24

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1 BY MS. PAPANTONIO:
2 Q. We have actually seen NDMA in
3 Torrent's valsartan that fell as high as
4 200 ppm. Do you remember that?
5 A. I don't recall specifically but
6 there were higher values than 37 and 39 in
7 some of those tables, yes.
8 Q. All right. And so this is the
9 FDA, this is the first time you become
10 aware of NDMA present in Torrent's
11 valsartan?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: In
15 Torrent's drug product for
16 amlodipine/valsartan/
17 hydrochlorothiazide, yes, this is
18 the first that we've seen test
19 results implying that this impurity
20 is there.
21 BY MS. PAPANTONIO:
22 Q. And the FDA is providing you
23 information on these tests?
24 A. FDA is providing us information

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1 on these results, yes.
2 Q. In other words, you had to rely
3 on the FDA to do your testing, because
4 Torrent did not have the capabilities of
5 doing so?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: It was
9 something that was in progress at
10 Torrent, and again, we had been
11 trying to find further information
12 from FDA on how they were testing
13 as well to try and help move our
14 work along also.
15 BY MS. PAPANTONIO:
16 Q. Right. If you look down from
17 the third paragraph to the bottom, it says
18 "Dawn actually requested some details on
19 the method they are using and the FDA
20 agreed to share that information." Right?
21 So let me ask you, had you asked the FDA
22 for their method on how to test weeks ago,
23 weeks before this, you would have learned
24 that NDMA was in Torrent's valsartan,

<p style="text-align: right;">Page 342</p> <p>1 right?</p> <p>2 MS. NAGLE: Objection,</p> <p>3 form.</p> <p>4 THE WITNESS: Kind of</p> <p>5 two, a couple of parts to that, I</p> <p>6 guess. I think I did ask FDA prior</p> <p>7 to this for details, and again,</p> <p>8 trying to understand FDA's method</p> <p>9 is just kind of part of the work</p> <p>10 that would have to be done to</p> <p>11 confirm that it's an appropriate</p> <p>12 method to use on our specific</p> <p>13 tablets.</p> <p>14 BY MS. PAPANTONIO:</p> <p>15 Q. Well, you know it's an</p> <p>16 appropriate method to use on your specific</p> <p>17 tablets, because the FDA tested Torrent</p> <p>18 specific tablets.</p> <p>19 MS. NAGLE: Objection,</p> <p>20 form.</p> <p>21 MS. PAPANTONIO:</p> <p>22 Correct?</p> <p>23 THE WITNESS: No, so</p> <p>24 again, without knowing details</p>	<p style="text-align: right;">Page 344</p> <p>1 own to test for NDMA, but yet you're</p> <p>2 questioning the accuracy of FDA?</p> <p>3 MS. NAGLE: Objection,</p> <p>4 form.</p> <p>5 THE WITNESS: You know,</p> <p>6 I think you're casting my</p> <p>7 questioning of data in a very</p> <p>8 negative light. You know, whenever</p> <p>9 you get data, you have to</p> <p>10 understand where it's coming from</p> <p>11 and understand its basis or else</p> <p>12 you may make poor decisions.</p> <p>13 BY MS. PAPANTONIO:</p> <p>14 Q. Okay. But you weren't even in</p> <p>15 a position where you could understand your</p> <p>16 own data, because you did not have it at</p> <p>17 this point?</p> <p>18 MS. NAGLE: Objection,</p> <p>19 form.</p> <p>20 THE WITNESS: The</p> <p>21 method, again, internally that</p> <p>22 Torrent was trying to develop was</p> <p>23 not at a stage of being able to</p> <p>24 detect these small quantities.</p>
<p style="text-align: right;">Page 343</p> <p>1 behind the method, and some of the</p> <p>2 things that go into that type of</p> <p>3 analytical development, we can't</p> <p>4 judge whether this 37, 39, whether</p> <p>5 these numbers are actually accurate</p> <p>6 without knowing more behind the</p> <p>7 method details.</p> <p>8 BY MS. PAPANTONIO:</p> <p>9 Q. Are you questioning the</p> <p>10 accuracy of the FDA's tests right now?</p> <p>11 MS. NAGLE: Objection,</p> <p>12 form.</p> <p>13 THE WITNESS: You always</p> <p>14 have to look at data and understand</p> <p>15 where it comes from. So, yeah, I'm</p> <p>16 saying, again, based on analytical</p> <p>17 procedures, the way methods get</p> <p>18 developed and validated to deem</p> <p>19 them appropriate, we don't know how</p> <p>20 accurate that number is without</p> <p>21 understanding more details.</p> <p>22 BY MS. PAPANTONIO:</p> <p>23 Q. And just to be clear, at this</p> <p>24 point, you don't even have a test of your</p>	<p style="text-align: right;">Page 345</p> <p>1 BY MS. PAPANTONIO:</p> <p>2 Q. Not at a stage where you could</p> <p>3 argue with the FDA over these testing</p> <p>4 levels?</p> <p>5 MS. NAGLE: Objection,</p> <p>6 form.</p> <p>7 MS. PAPANTONIO: Right.</p> <p>8 THE WITNESS: Not -- we</p> <p>9 did not have any additional data at</p> <p>10 this point to be able to discuss</p> <p>11 with them in detail the specifics</p> <p>12 of their results.</p> <p>13 BY MS. PAPANTONIO:</p> <p>14 Q. Okay. Let's switch gears a</p> <p>15 little bit and go to this next line where</p> <p>16 it says "Per Dawn, we will quarantine the</p> <p>17 products we are in possession with and</p> <p>18 discuss with TPL QA the recall." Right?</p> <p>19 So at this point, August 16, Torrent had</p> <p>20 not quarantined its valsartan product?</p> <p>21 A. I would have to go back and</p> <p>22 look at details, I mean, at least in</p> <p>23 relation to this drug product for the</p> <p>24 amlodipine/valsartan/hydrochlorothiazide,</p>

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1 it doesn't appear that we had at least
2 quarantined everything that was in our
3 possession.
4 Q. That means that between
5 August 3rd, when you got notice that NDMA
6 was in your product, to two weeks later,
7 August 16, you continued to put valsartan
8 on the market?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: And as I
12 mentioned before, the notice on
13 August 3 did not give us
14 appropriate levels of information
15 to understand how much of that
16 impurity may be present or in what,
17 within which batches.
18 MS. PAPANTONIO: Do you
19 want to take a five-minute break?
20 MS. NAGLE: Sure.
21 THE WITNESS: Sure.
22 THE VIDEOGRAPHER: 4:25,
23 we are off the video record.
24 - - - - -

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1 (A recess was taken at this time.)
2 - - - - -
3 THE VIDEOGRAPHER: 4:37,
4 we are on the video record.
5 BY MS. PAPANTONIO:
6 Q. Okay. We're going to call up
7 LP 1144, and that's marked as Torrent 27.
8 Okay. We can see that this is the date
9 August 22, right?
10 A. Of 2018, yes.
11 Q. Of 2018. And what the title
12 says is "additional lots added," and that's
13 added to the FDA recall, right?
14 A. I believe so.
15 Q. All right. Below it says "The
16 recall has been completed and FDA has
17 terminated this recall." And it says
18 additional lots added, Torrent
19 Pharmaceuticals, right? So on August 22,
20 Torrent Pharmaceuticals recalls its
21 versions of valsartan, correct?
22 A. At least the listed batches
23 that were recalled on that date, yes.
24 Q. Okay. And so this date is 19

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1 days after Torrent got notice from ZHP of
2 contamination in Torrent's valsartan
3 products, right?
4 A. This is 19 days after ZHP
5 notified Torrent that potentially some of
6 the old route of synthesis batches
7 contained the impurity, not necessarily the
8 Torrent batches had been specifically known
9 to contain that impurity.
10 Q. And then the FDA lists all of
11 the batches of Torrent valsartan that have
12 been recalled, right? And we see there are
13 about 13 pages of batches that have been
14 recalled, if we just scroll through this
15 real quick. Right? So we're looking at
16 all the batches of Torrent valsartan that
17 have NDMA above the FDA threshold, right?
18 A. Yeah, I don't remember if it's
19 one impurity or both of the impurities, but
20 yes, impurities above the threshold.
21 Q. Right. Because, Ms. Chitty,
22 you know there was also another impurity in
23 Torrent's valsartan, right? Look at 1109.
24 Let's pull up LP 1109. Do you recognize

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1 this email?
2 A. Not specifically, but it's
3 addressed to me.
4 MS. PAPANTONIO: This is
5 going to be Torrent 93.
6 - - - - -
7 (Email dated 9/7/18 Bates
8 TORRENT-MDL2875-006044834 marked
9 Torrent Exhibit 93 for
10 identification.)
11 - - - - -
12 BY MS. PAPANTONIO:
13 Q. We can see that this email is
14 from the FDA, right? Right here at the
15 bottom.
16 A. Correct.
17 Q. And this was sent on
18 September 7, correct?
19 A. Yes.
20 Q. So that is about two weeks
21 after Torrent had recalled its valsartan
22 for NDMA?
23 A. Correct.
24 Q. Okay. And now, two weeks

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1 later, the FDA is telling Torrent that
2 another contaminant has been found in its
3 batches of valsartan, right, NDEA?
4 A. Yes, that's what's stated here.
5 Q. Right. So at this point, had
6 Torrent -- did Torrent have the
7 capabilities to test its product for
8 nitrosamines?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: I'm not
12 sure. I would have to look at
13 other communications to kind of put
14 it in context, so.
15 BY MS. PAPANTONIO:
16 Q. But what we do know is that it
17 is the FDA telling Torrent that there's
18 another nitrosamine in their product,
19 right?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: In this
23 email, yes, that appears to be the
24 topic.

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1 BY MS. PAPANTONIO:
2 Q. Is this the first time on
3 August -- or September 7 that you learned
4 NDEA was in Torrent's valsartan?
5 A. I'm not sure. Again, I would
6 have to look through kind of all of those
7 communications.
8 Q. But just to be fair, you have
9 no memory of NDEA being in Torrent
10 valsartan up until this point?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: I just
14 don't remember.
15 BY MS. PAPANTONIO:
16 Q. Okay. Do you know what NDEA
17 is?
18 A. It's a similar structure
19 impurity as to the first one.
20 Q. Were you aware that NDEA is
21 actually more potent than NDMA?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: At the

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1 time, no.
2 BY MS. PAPANTONIO:
3 Q. Are you aware that the FDA --
4 are you aware that NDEA is -- let me move
5 to strike.
6 Are you aware that the
7 threshold for NDEA is actually lower than
8 the FDA threshold for NDMA?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: I think we
12 saw that earlier in one of the
13 tables that was presented.
14 BY MS. PAPANTONIO:
15 Q. And were you aware that that
16 was because it is a more potent carcinogen
17 than NDEA?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: I am now.
21 I don't recall if I was at the
22 time.
23 BY MS. PAPANTONIO:
24 Q. So at this point, the FDA is

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1 telling Torrent, there's another carcinogen
2 in valsartan. Was Torrent able to confirm
3 this fact based on -- by using testing?
4 MS. NAGLE: Objection.
5 Form and foundation.
6 THE WITNESS: As of this
7 day, I'm not sure. Again, there
8 were lots of communications, so I
9 just can't recall from memory.
10 MS. PAPANTONIO: You
11 have no idea if Torrent had
12 actually developed a testing method
13 for its valsartan by September 7,
14 2018?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: I don't
18 recall specifically just because it
19 was so long ago.
20 BY MS. PAPANTONIO:
21 Q. Okay. Now -- let's put that
22 away. Ms. Chitty, remember at the
23 beginning of this, I told you that we were
24 going to write down all of these dates in a

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1 timeline form so we can condense kind of
2 what happened here?
3 A. Sure.
4 Q. We're going to look at that
5 now. Okay? Can we pull up the timeline
6 document? Okay. We're going to have to
7 zoom on this a little bit, because it's a
8 bit long. Okay. I want to start with that
9 first day. Let's zoom in there.
10 MS. NAGLE: Sorry,
11 Counsel, before you start asking
12 questions, does this have an
13 exhibit number?
14 MS. PAPANTONIO: Yeah,
15 Torrent 94.
16 - - - - -
17 (Torrent Recall Timeline marked
18 Chitty Exhibit 94 for identification.)
19 - - - - -
20 MS. NAGLE: Okay. Thank
21 you.
22 BY MS. PAPANTONIO:
23 Q. Okay. Now, this first date,
24 June 20, that's when ZHP notifies Torrent

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1 of NDMA in the valsartan API. Do you
2 remember we talked about that?
3 A. I remember that date and that
4 notification, I don't recall it
5 specifically mentions NDMA at that point.
6 Q. Okay. But we know that this
7 was what put you on notice of the genotoxic
8 impurity, right?
9 A. Potentially genotoxic impurity
10 I believe is the phrase that they used.
11 Q. And then we saw that 16 days
12 later, Torrent learns of the European
13 recall of valsartan, right?
14 A. Again, I don't recall the
15 specific date. That seems roughly about
16 right.
17 Q. Okay. So between June 20 and
18 July 6, that's 16 days, right?
19 A. I don't have a calendar in
20 front of me, but close to 16, I'm sure.
21 Q. But what we do know is that
22 during this time, Torrent is selling
23 valsartan?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: Correct.
3 We are selling valsartan-containing
4 products during this time.
5 BY MS. PAPANTONIO:
6 Q. During this time, Torrent is
7 communicating with customers that the
8 valsartan is not contaminated with NDMA?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: I don't
12 recall those specific dates of
13 those communications.
14 BY MS. PAPANTONIO:
15 Q. What we do know is that during
16 this time between June 20 and June 6 [sic],
17 Torrent has not yet developed a test method
18 to determine whether or not NDMA is in its
19 product, right?
20 A. Between June 20 and July 6? I
21 think you said June -- I think you said
22 June 6.
23 Q. Oops, sorry.
24 A. During that time, correct, we

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1 have not developed a method to accurately
2 detect the impurity.
3 Q. Okay. And now let's jump down
4 from June 20 to July 13 when the FDA makes
5 that first initial recall for certain
6 valsartan manufacturers, right? Do you
7 remember that?
8 A. Yeah, I believe it was around
9 the 13th.
10 Q. Yeah, we can see that that's 23
11 days after Torrent got notice of a
12 potential genotoxic impurity, right?
13 A. Correct, that's roughly 23
14 days.
15 Q. And during this time, Torrent
16 continued to sell its valsartan product,
17 right, it didn't recall the product?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: During
21 that time, it did not, Torrent did
22 not recall the product?
23 BY MS. PAPANTONIO:
24 Q. Yeah.

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1 A. I can't, again, specifically
 2 talk to whether product was under hold at a
 3 certain point and I also can't speak to
 4 other countries outside of the U.S. as to
 5 what they were doing.
 6 Q. Okay. In terms of U.S.
 7 customers, what we do know is that Torrent
 8 was communicating with U.S. customers that
 9 there was no NDMA in the product, right?
 10 MS. NAGLE: Objection,
 11 form.
 12 THE WITNESS: From a
 13 timeline standpoint, I'm not -- I
 14 don't remember exactly when those
 15 communications were happening, but
 16 sometime in July, we were
 17 communicating with customers what
 18 we knew at the time.
 19 BY MS. PAPANTONIO:
 20 Q. And had Torrent tested its
 21 product for NDMA on July 13, 2018, it would
 22 have found that the product was -- had
 23 contained NDMA, right?
 24 MS. NAGLE: Objection,

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1 form.
 2 THE WITNESS: Again, we
 3 did not have an appropriate method
 4 in the middle of July to be able to
 5 detect those impurities.
 6 BY MS. PAPANTONIO:
 7 Q. If you had an appropriate
 8 method, you would have learned that NDMA
 9 was in Torrent's valsartan, correct?
 10 MS. NAGLE: Objection,
 11 form.
 12 THE WITNESS: It was not
 13 in all batches or all product.
 14 Again, I can't really speculate on
 15 details to say all products.
 16 BY MS. PAPANTONIO:
 17 Q. Let me rephrase. If you had
 18 tested Torrent's valsartan product on
 19 July 13, 2018, you would have found that
 20 NDMA was present in some of Torrent's
 21 valsartan batches?
 22 MS. NAGLE: Objection,
 23 form.
 24 THE WITNESS: As of that

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1 time frame, we did not have the
 2 ability to test to detect the
 3 impurities.
 4 BY MS. PAPANTONIO:
 5 Q. It's not my question of whether
 6 you had the ability. If you had tested the
 7 valsartan API, Torrent would have found
 8 that some batches were contaminated with
 9 NDMA?
 10 MS. NAGLE: Objection,
 11 form.
 12 THE WITNESS: Again, it
 13 only impacted certain batches, so I
 14 don't know -- I can't kind of
 15 blanket state that we would have
 16 definitely seen that, because I
 17 don't know what we had in stock at
 18 that time.
 19 BY MS. PAPANTONIO:
 20 Q. But you are aware that on
 21 July 13, there were some batches that
 22 contained NDMA?
 23 MS. NAGLE: Objection,
 24 form.

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1 THE WITNESS: Again, I'm
 2 not aware if there were batches
 3 that Torrent had of API in its
 4 possession that had NDMA present on
 5 that date.
 6 BY MS. PAPANTONIO:
 7 Q. And if you had tested those
 8 contaminated batches, you would have
 9 learned that there were levels of NDMA that
 10 were above the FDA threshold?
 11 MS. NAGLE: Objection,
 12 form.
 13 THE WITNESS: Again, I
 14 just -- I can't speculate on a
 15 theoretical. I don't know, I don't
 16 know what batches we had. There
 17 was impurities in some batches and
 18 no impurities in others. So
 19 without talking, you know, kind of
 20 very specifically and having data
 21 and results from further in time, I
 22 just can't say what you, obviously,
 23 want me to say.
 24

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1 BY MS. PAPANTONIO:
2 Q. Well, Ms. Chitty, let me just
3 get this straight. We're not speaking in
4 theory. This is not theoretical. You're
5 aware that Torrent's valsartan was
6 contaminated with NDMA, right, across the
7 board?
8 MS. NAGLE: Objection,
9 form.
10 THE WITNESS: No, that's
11 not an accurate statement.
12 BY MS. PAPANTONIO:
13 Q. All of Torrent's valsartan had
14 NDMA and/or NDEA?
15 MS. NAGLE: Objection,
16 form.
17 BY MS. PAPANTONIO:
18 Q. You had no idea?
19 A. No, I don't believe it was all
20 of Torrent's valsartan. As I said, I think
21 there were some batches that had
22 contamination and some that did not.
23 Q. But what we can agree on is
24 that on July 3, 2018, Torrent did not have

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1 the capability of testing its valsartan to
2 verify this?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: In the
6 middle of July, Torrent did not
7 have a method to adequately test
8 API or finished goods or adequately
9 measure and accurately measure
10 potential impurities.
11 BY MS. PAPANTONIO:
12 Q. Okay. Let's go to the next
13 one. July 17, when you're telling your
14 colleagues at Torrent that we really need a
15 method to evaluate these products
16 ourselves, had you tested Torrent's
17 batches, Torrent would have found that some
18 NDMA was in those batches?
19 MS. NAGLE: Objection,
20 form.
21 THE WITNESS: Again, it
22 was in some batches and not others.
23 So I can't say that if we had
24 tested what we had in our

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1 possession that day, it would have
2 come back as showing that impurity.
3 BY MS. PAPANTONIO:
4 Q. In your role as a regulatory
5 official, did you ever lay eyes on a batch
6 that did not contain NDMA or NDEA?
7 MS. NAGLE: Objection,
8 form.
9 THE WITNESS: I believe
10 there were batches that did not
11 contain either impurity, yeah.
12 BY MS. PAPANTONIO:
13 Q. Which one?
14 A. Did I lay eyes on them? No, I
15 don't lay eyes on product. I can't recall
16 batch numbers from three, four years ago.
17 Q. All right. Let's go back to
18 what we can agree on. On July 17, 27 days
19 after Torrent received notice of a
20 genotoxic impurity, Torrent still does not
21 have a method to evaluate whether or not
22 its valsartan has NDMA; is that correct?
23 MS. NAGLE: Objection to
24 form.

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1 THE WITNESS: At that
2 time, that's correct. Our method
3 was still not able to detect the
4 impurities at those levels.
5 BY MS. PAPANTONIO:
6 Q. Okay. July 19, when Torrent
7 releases the valsartan out of quarantine,
8 at this point, Torrent still does not have
9 a method to detect whether or not NDMA is
10 present in its valsartan, correct?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: I believe
14 at that time, the method was still
15 not available, correct.
16 BY MS. PAPANTONIO:
17 Q. And at this point, had you
18 tested all of the Torrent batches, you
19 would have found that some of those batches
20 contained levels of NDMA above the FDA
21 threshold, correct?
22 MS. NAGLE: Objection,
23 form.
24 THE WITNESS: Again, I

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1 don't know which batches were in
2 quarantine at that point, so I
3 can't say that they all would have
4 contained that impurity.
5 BY MS. PAPANTONIO:
6 Q. I'm not asking which batches.
7 I'm asking if you tested all of Torrent's
8 batches, some of those batches would have
9 come back positive for NDMA; is that
10 correct?
11 MS. NAGLE: Objection.
12 Form and foundation.
13 THE WITNESS: Again, at
14 that point in time, I don't know
15 what those batches were, so they
16 may not have been batches that
17 eventually were shown to contain
18 the impurity.
19 BY MS. PAPANTONIO:
20 Q. But you know that Torrent's
21 valsartan was contaminated with high levels
22 of NDMA?
23 MS. NAGLE: Objection,
24 form.

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1 THE WITNESS: No, again,
2 only specific batches were
3 eventually shown to have the
4 impurity. At this point, we're not
5 aware that the old route of
6 synthesis batches contain that
7 impurity.
8 BY MS. PAPANTONIO:
9 Q. Let's pull up LP 1065. Pull up
10 LP 1218. All right. Ms. Chitty, I just
11 want to make sure we're absolutely clear on
12 what was happening at Torrent.
13 MS. NAGLE: I'm sorry to
14 interrupt again, can I just get the
15 exhibit number for the record,
16 please?
17 MS. PAPANTONIO: Yup,
18 one second.
19 MS. NAGLE: Thank you.
20 MS. PAPANTONIO: All
21 right. This is Torrent 79.
22 MS. NAGLE: Thank you.
23 BY MS. PAPANTONIO:
24 Q. Okay. We've already looked at

Page 368

1 this document earlier today, Ms. Chitty.
2 Do you remember it?
3 A. Not specifically. We've looked
4 at a lot today.
5 Q. Okay. Well, let's rehash what
6 we're looking at. At the very top, it says
7 "finished dose goods," right?
8 A. Yes.
9 Q. And these are finished dose
10 batches made by Torrent Pharmaceuticals,
11 right?
12 A. Correct, manufactured at our
13 Indrad plant.
14 Q. At Indrad. Okay. And then if
15 you look at these numbers, let's look at
16 the NDMA results at TPL. Do you see that?
17 A. Yes.
18 Q. All right. Do you see that all
19 of these batches tested positive for NDMA?
20 A. I mean, it's noted there on
21 some of those that there's below 0.25,
22 which is probably, like, the limit of
23 detection, I would guess, so when it's
24 below a limit of detection, that implies

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1 that it's not necessarily there.
2 Q. No, it implies that it's there,
3 just that it's below detection, correct?
4 MS. NAGLE: Objection.
5 Form and foundation.
6 THE WITNESS: No, I
7 would disagree, it does not imply
8 that it's necessarily there. It
9 implies that the method can't tell
10 whether it's there or not.
11 BY MS. PAPANTONIO:
12 Q. All right. We're going to go
13 to LP 1337. All right. This has already
14 been marked. Yeah, I'm sorry, we're trying
15 to get situated here.
16 MS. NAGLE: Okay. It's
17 just for the record, I'm sorry to
18 keep bugging you.
19 MS. PAPANTONIO: Huh?
20 MS. NAGLE: I said I'm
21 sorry to keep bugging you, it's
22 just for the record.
23 MS. PAPANTONIO: Okay.
24 So, Madeline, look up and see what

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1 number. We're going to mark this
2 Torrent Exhibit 95.
3 MS. NAGLE: Thank you.
4 EXHIBIT TECH: I have
5 this marked as Torrent 78.
6 MS. PAPANTONIO:
7 Perfect. We have multiple copies
8 here, so we couldn't figure out
9 which one it was, that was the
10 hassle.
11 Okay. We looked at this
12 document earlier, Ms. Chitty, you
13 saw that these batch numbers were
14 later put into Torrent finished
15 dose batches. Do you remember
16 that?
17 THE WITNESS: I believe
18 I remember looking at this document
19 before. I'm not clear if these
20 were actually used in all finished
21 dose batches or not.
22 BY MS. PAPANTONIO:
23 Q. But we do know that the batch
24 number is assigned an AR number, right? Do

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1 you see that?
2 A. Yes.
3 Q. And that AR number is assigned
4 by Torrent Pharmaceuticals, right?
5 A. Correct.
6 Q. That means that this batch is
7 in Torrent's possession?
8 A. Correct.
9 Q. And if we're looking at the
10 testing levels on this document, we can see
11 that there is NDMA content in parts per
12 million that is in the 100s, Ms. Chitty.
13 Do you see that?
14 A. Some of them are in the
15 hundreds, yes.
16 Q. Now, just to be clear, that's a
17 lot more than .3 parts per million, right?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: Yes, 100
21 is more than .3.
22 BY MS. PAPANTONIO:
23 Q. And had this batch gone into a
24 finished dose batch, it would have been

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1 later distributed to a consumer, right?
2 MS. NAGLE: Objection.
3 Form and foundation.
4 THE WITNESS: If the
5 finished dose batch met the current
6 testing specifications at the time,
7 it would have been released to
8 market, yes.
9 BY MS. PAPANTONIO:
10 Q. So my question, Ms. Chitty, is
11 do you understand that Torrent was
12 supplying valsartan with NDMA parts per
13 million in the 100s to consumers?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: Again,
17 this is -- these are API results, I
18 believe, based on the context of
19 the document. At no point did
20 Torrent knowingly distribute
21 product with above set limits into
22 the market. As soon as they became
23 aware of limits and the ability to
24 test, product that was over the

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1 allowable limits, and there are
2 allowable limits, was recalled.
3 BY MS. PAPANTONIO:
4 Q. Okay. Ms. Chitty, you said at
5 no point did Torrent knowingly distribute
6 product that was over the FDA limit. Okay.
7 That's what you said, right?
8 A. Correct.
9 Q. And we agree that to know
10 information, you have to have all of the
11 data, right?
12 A. You have to make decisions
13 based on data you have in your possession
14 at the time.
15 Q. And if you want to know about
16 something, you actually have to seek out
17 additional data at times, right?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: Seeking
21 information is one way to obtain
22 data and in this case, we were
23 obtaining information from multiple
24 sources.

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1 BY MS. PAPANTONIO:
2 Q. Right. And a sure proof way to
3 obtain data is to test a product, right?
4 MS. NAGLE: Objection to
5 form.
6 THE WITNESS: And that's
7 what we were working towards trying
8 to be able to do.
9 BY MS. PAPANTONIO:
10 Q. You were working towards it,
11 but as far as what we've seen here today,
12 you were never able to test the product; is
13 that correct?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: I don't
17 think that we were never able to
18 test the product, because didn't
19 you just show me results that were
20 generated at TPL?
21 BY MS. PAPANTONIO:
22 Q. Between the time Torrent was --
23 at the time Torrent was recalled, we did
24 not have the ability to test the product;

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1 isn't that right?
2 A. At the initial recall, the
3 first recall date of, I think that was
4 August 22nd of 2018, at that time, they did
5 not have the ability to accurately test for
6 the impurities.
7 Q. So until August 22nd when the
8 valsartan was recalled, Torrent knowingly
9 allowed its valsartan to be on the market
10 without testing it to determine if NDMA was
11 in the product?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: Again, we
15 did not know of any positive or
16 over-specification results for a
17 product we had on the market at the
18 time.
19 BY MS. PAPANTONIO:
20 Q. But, Ms. Chitty, do you
21 understand that you did not know because
22 you did not test the product?
23 A. The product wasn't able to be
24 tested at that point based on the lack of

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1 method, you know, within our own labs.
2 Q. And you understand that
3 multiple manufacturers had tested their
4 products successfully and found NDMA prior
5 to August 22nd, you know that, right?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: No, I
9 don't know who was testing other
10 manufacturers' products.
11 BY MS. PAPANTONIO:
12 Q. In order to learn information,
13 all you need to do is ask, right? And we
14 established that you never asked those
15 manufacturers how they tested their product
16 for NDMA.
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: That's not
20 a question. That's a statement.
21 Do you have a question?
22 BY MS. PAPANTONIO:
23 Q. Do you agree with that
24 statement, that Torrent never asked other

Page 377

1 manufacturers how to test for NDMA?
2 A. As I stated before, I
3 personally was not aware of other
4 manufacturers being asked. I can't say
5 conclusively whether somebody else within
6 the company had asked or not.
7 Q. And Torrent has got
8 laboratories all across the world, none of
9 those laboratories tested for NDMA, right?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: Again, I'm
13 aware of the laboratories that
14 Torrent has within India and our
15 partners, partner laboratories
16 within India, and at the time, none
17 of those labs that I'm aware of
18 were able to test accurately for
19 the presence of these impurities.
20 BY MS. PAPANTONIO:
21 Q. And we've established that for
22 two months, you were not able to develop a
23 test in-house, but we did talk about
24 independent testing sites that you could

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1 have sent your product to, right, Torrent
 2 never did that?
 3 MS. NAGLE: Objection,
 4 form.
 5 THE WITNESS: And as I
 6 mentioned at the time, this is not
 7 an off the shelf kind of test. You
 8 don't just randomly send it to the
 9 corner lab to get these tests done.
 10 It was complex. It's difficult.
 11 You know, you may be unaware, but
 12 typically developing a method takes
 13 months and months of time. So it's
 14 not out of the -- I would say
 15 unusual that this activity was
 16 going on for potentially a couple
 17 of months without satisfactory
 18 results.
 19 BY MS. PAPANTONIO:
 20 Q. But you are aware that other
 21 organizations were able to do it
 22 significantly faster than Torrent, correct?
 23 MS. NAGLE: Objection,
 24 form.

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1 THE WITNESS: And,
 2 again, as I stated before, I don't
 3 really know what other companies
 4 were doing nor where they were
 5 getting results from.
 6 BY MS. PAPANTONIO:
 7 Q. And Torrent never reached out
 8 to any of these other companies to see if
 9 they had already developed a method, did
 10 they?
 11 MS. NAGLE: Objection,
 12 form.
 13 THE WITNESS: I
 14 personally did not and I'm not
 15 aware of what everyone else in the
 16 company was doing or not doing in
 17 that regard.
 18 BY MS. PAPANTONIO:
 19 Q. You're not aware of any Torrent
 20 employee reaching out to independent labs
 21 to determine whether or not they had
 22 already developed a method for this?
 23 MS. NAGLE: Objection,
 24 form.

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1 THE WITNESS:
 2 Personally, no, I'm not aware of
 3 whether that happened or not.
 4 BY MS. PAPANTONIO:
 5 Q. What you do know is that
 6 Torrent waited to develop its own method
 7 and that method had still not been
 8 developed on August 22?
 9 MS. NAGLE: Objection,
 10 form.
 11 THE WITNESS: I wouldn't
 12 categorize it as Torrent waited.
 13 They were, to my knowledge,
 14 actively working on trying to
 15 develop the new method to
 16 adequately be able to test for the
 17 impurities.
 18 BY MS. PAPANTONIO:
 19 Q. And the FDA beat them to it,
 20 right?
 21 MS. NAGLE: Objection,
 22 form.
 23 THE WITNESS: The FDA
 24 did seem to have a method for

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1 testing for the impurities prior to
 2 Torrent had developed their method.
 3 BY MS. PAPANTONIO:
 4 Q. Okay, let's take this down.
 5 And switch gears. We're going to talk
 6 about ZHP. One second. 1192. LP 1192,
 7 please. And this is Torrent 22.
 8 All right. Ms. Chitty, have
 9 you reviewed the 2017 inspection reports
 10 that documents the FDA's inspection of ZHP
 11 in 2017?
 12 A. I don't recall specifically
 13 having seen this inspection report.
 14 Q. Are you aware of anyone else in
 15 Torrent that might have reviewed ZHP's
 16 inspection report?
 17 A. I don't know.
 18 Q. Okay. We can see that this is
 19 a document created by the FDA, right, in
 20 the top right corner?
 21 A. Correct.
 22 Q. FDA is a U.S. government
 23 organization, right?
 24 A. Correct.

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1 Q. Therefore, this is considered a
 2 public document under the Freedom of
 3 Information Act, right?
 4 MS. NAGLE: Objection.
 5 Form and foundation.
 6 THE WITNESS: Yeah, I
 7 really don't know what falls under
 8 the purview of FOIA, so.
 9 BY MS. PAPANTONIO:
 10 Q. Well, in your capacity as
 11 regulatory affairs manager or director, you
 12 could have requested this document --
 13 MS. NAGLE: Objection.
 14 MS. PAPANTONIO: -- from
 15 the FDA?
 16 MS. NAGLE: I'm sorry.
 17 Objection, form.
 18 THE WITNESS: In the
 19 past, I have requested inspection
 20 reports, yes.
 21 BY MS. PAPANTONIO:
 22 Q. Okay. And those are -- okay.
 23 Okay. So an inspection report is an
 24 investigation conducted by the FDA, right?

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1 A. It's a report that summarizes
 2 an inspection that has typically been done
 3 by FDA.
 4 Q. Okay. And in this case, the
 5 FDA is conducting an inspection of ZHP,
 6 right?
 7 A. Yes, it appears that way.
 8 Q. And the inspection date is May
 9 of 2017?
 10 A. Yes.
 11 Q. And at this time, May of 2017,
 12 ZHP is supplying valsartan API to Torrent,
 13 right?
 14 A. Yeah, I believe so.
 15 Q. Now, earlier, we talked about
 16 how Torrent was buying API from ZHP because
 17 it's cheap. Remember that conversation?
 18 MS. NAGLE: Objection,
 19 form.
 20 THE WITNESS: I remember
 21 discussing that we were buying API
 22 from ZHP that was less costly than
 23 our other supplier.
 24

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1 BY MS. PAPANTONIO:
 2 Q. Right. And because, like you
 3 told me, Torrent is also a business, right,
 4 it has to make financial decisions?
 5 A. Correct.
 6 Q. Got to save money where they
 7 can?
 8 MS. NAGLE: Objection,
 9 form.
 10 THE WITNESS: You make
 11 business decisions based on
 12 economic factors.
 13 BY MS. PAPANTONIO:
 14 Q. And in order -- even if
 15 something is cheaper, it can still be good
 16 quality, but you have to follow up on that,
 17 right, as a business?
 18 MS. NAGLE: Objection,
 19 form.
 20 THE WITNESS: Price does
 21 not necessarily dictate quality,
 22 correct.
 23 BY MS. PAPANTONIO:
 24 Q. All right. Now, here the FDA

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1 is investigating ZHP, but the FDA is not
 2 the only organization that can conduct
 3 investigations on drug facilities like ZHP,
 4 right?
 5 MS. NAGLE: Objection.
 6 Form and foundation.
 7 THE WITNESS: I mean, I
 8 guess other regulators can do
 9 inspections is what you're
 10 implying --
 11 BY MS. PAPANTONIO:
 12 Q. Well, actually, let me
 13 rephrase. Torrent can conduct audits on
 14 its contractors, right?
 15 MS. NAGLE: Objection.
 16 Form and foundation.
 17 THE WITNESS: Yes, with
 18 the agreement of those vendors,
 19 Torrent can do inspections.
 20 BY MS. PAPANTONIO:
 21 Q. So with that being said,
 22 Torrent can conduct an audit of ZHP if it
 23 wanted to, right?
 24 A. With agreement of the vendor or

Page 386

1 the site, yes.

2 Q. Right. So if Torrent wanted to

3 verify that its API is good quality, it

4 could audit ZHP?

5 A. It could.

6 Q. Okay. So let's take a look at

7 what the FDA found here. This is May 2017,

8 so we're about a year before this NDMA

9 contamination occurred, right?

10 A. Before the issue became known,

11 yes.

12 Q. Right. Okay. And so looking

13 at page 2, what we see is that the FDA says

14 that "The current investigation -- or

15 inspection was a system based approach,

16 with a focus on Quality, Laboratory

17 control, Facilities and Equipment and

18 Production Systems." Why is it important

19 to focus on the quality of a contractor or

20 vendor?

21 MS. NAGLE: Objection,

22 form.

23 THE WITNESS: I think

24 this means that it was focusing on

Page 387

1 the quality system.

2 BY MS. PAPANTONIO:

3 Q. Okay. What does that mean?

4 A. Typically, in manufacturing,

5 the quality system is the procedures that

6 govern all of the various activities used

7 when making a product.

8 Q. Okay. What are laboratory

9 controls?

10 A. Those are the procedures that

11 are in place specifically related to the

12 laboratories to make sure, for instance,

13 equipment is, you know, calibrated, you

14 know, solvents are within date, those kinds

15 of items.

16 Q. Okay. And we can see that the

17 FDA came up with three conclusions. Do you

18 see that? The first conclusion is that

19 "Appropriate controls are not implemented

20 over Quality Control to ensure the

21 integrity of the analytical system." When

22 was the first time you learned that ZHP

23 could not ensure integrity of its

24 analytical system?

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1 A. Again, I don't know if I've

2 specifically seen this report, since it

3 wasn't part of my job to kind of vet

4 suppliers and contractors.

5 Q. Before today, had you ever

6 learned that ZHP's anomalies were not

7 investigated in their analytical testing?

8 A. I'm not familiar with that

9 topic, no.

10 Q. As a VP of regulatory affairs,

11 did anyone ever tell you that ZHP lacked

12 integrity in their analytical testing

13 system?

14 MS. NAGLE: Objection,

15 form.

16 THE WITNESS: I don't

17 recall a specific instance where I

18 was notified of that, but again,

19 it's been a while.

20 BY MS. PAPANTONIO:

21 Q. Is that information that would

22 be important for you to learn?

23 MS. NAGLE: Objection,

24 form.

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1 THE WITNESS: It's

2 information I would like to know.

3 Again, there's many units within

4 Torrent that are responsible for

5 overseeing quality of suppliers on

6 these types of issues.

7 BY MS. PAPANTONIO:

8 Q. Who is responsible at Torrent

9 for overseeing ZHP?

10 MS. NAGLE: Objection,

11 form.

12 THE WITNESS: I mean,

13 specifically, I'm not sure, but

14 there's quality unit

15 responsibilities and then I think

16 there's a separate group that does

17 vendor qualification and oversight

18 as well.

19 BY MS. PAPANTONIO:

20 Q. Okay. The second thing that

21 the FDA concludes is that ZHP "Facilities

22 and equipment are not maintained to ensure

23 quality attributes of the drug product."

24 Now, just to be clear, ZHP is making

Page 390

1 Torrent's valsartan API in these
2 facilities, right?
3 MS. NAGLE: Objection.
4 Form and foundation.
5 THE WITNESS: I'm not
6 sure how many facilities ZHP has,
7 but it makes Torrent valsartan API
8 in one of their facilities.
9 BY MS. PAPANTONIO:
10 Q. Okay. Let's just go to the
11 fourth page really quick. Okay. On this
12 page, we can see the products that are
13 being manufactured at this facility that
14 the FDA is inspecting. Do you see that
15 first line where it says valsartan USP?
16 A. Yes.
17 Q. So this is the facility that
18 valsartan API is being made that the FDA is
19 investigating, okay?
20 A. It may be one of the
21 facilities. Again, I don't know the
22 details. They may have multiple sites and
23 could manufacture with that same DMF number
24 at multiple sites.

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1 Q. But what we can agree on is
2 this is the first time that you've heard
3 that ZHP facilities and equipment are not
4 maintained to ensure quality, right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: And,
8 agree. Again, me, personally, I
9 don't recall when I became aware of
10 this and I don't really know when
11 others within Torrent might or
12 might not have known about this.
13 BY MS. PAPANTONIO:
14 Q. Okay. Let's go back to the, or
15 the second page with these conclusions.
16 Okay. The third conclusion that the FDA
17 makes about ZHP facilities is that
18 "Invalidation of out-of-specification
19 results lack adequate scientific
20 justification." Have you ever heard that
21 before?
22 A. I've heard that phrase. I've
23 not necessarily been aware of it in
24 relation to ZHP specifically.

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1 Q. Let's break this down. What
2 does out of specification mean?
3 A. Out of specification means that
4 of all of the various tests you do, let's
5 say if you're getting ready to release API,
6 something does not meet the current
7 specification.
8 Q. Okay. And so when a drug is
9 out of specification, it means that's
10 something is wrong with it, right?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: It means
14 that it does not meet current
15 standards and so should not be
16 directly released for normal use.
17 BY MS. PAPANTONIO:
18 Q. And so this is telling us that
19 your API supplier invalidates
20 out-of-specification products without
21 scientific justification, right?
22 A. That is what, apparently, the
23 FDA inspectors observed on some product.
24 Q. And like you told us, Torrent

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1 has the ability to audit vendors like ZHP
2 at any time, right?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: Again, at
6 any time, I don't know, but with
7 coordination from the vendor, we
8 could audit.
9 BY MS. PAPANTONIO:
10 Q. So in May of 2017, before
11 this -- you learn of this recall, Torrent
12 could have audited ZHP with their
13 permission and found this information?
14 MS. NAGLE: Objection,
15 form.
16 THE WITNESS: I don't
17 know what Torrent would have found
18 had they audited. I mean, it's not
19 a requirement that you have to do
20 on-site audits of your vendors.
21 BY MS. PAPANTONIO:
22 Q. But it is a part of due
23 diligence, wouldn't you agree?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: It can be
3 a part of due diligence. Again,
4 it's not a required part of due
5 diligence.
6 BY MS. PAPANTONIO:
7 Q. But as a finished dose
8 manufacturer, you want to make sure that
9 you're getting quality ingredients from
10 your vendors, right?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: Yes, and
14 there are multiple ways of doing
15 that.
16 BY MS. PAPANTONIO:
17 Q. Right. One of those ways is
18 testing the product, which we know you
19 didn't do?
20 MS. NAGLE: Objection,
21 form.
22 THE WITNESS: We tested
23 our products, so.
24

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1 BY MS. PAPANTONIO:
2 Q. And then another way is
3 investigating the vendor site like the FDA
4 is doing here, right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: We can
8 audit. Again, it's not required.
9 BY MS. PAPANTONIO:
10 Q. And as far as you know, Torrent
11 never audited ZHP's facility in 2017?
12 A. In 2017, I really don't know.
13 I wasn't part of that group that does
14 audits, so.
15 Q. Who was in the group that does
16 audits? Were you able to give me any names
17 of those individuals?
18 A. Again, it's, I think, some
19 cooperative effort between the quality
20 assurance team and the vendor management
21 team.
22 Q. Okay. Let's go to page 14.
23 All right. Now, we can see on little
24 paragraph C right here, the FDA has

Page 396

1 concluded that "the following batches
2 exhibit out-of-trend results." What does
3 out of trend mean?
4 MS. NAGLE: Objection to
5 form.
6 THE WITNESS: Yeah,
7 that's a little outside of my kind
8 of knowledge base too.
9 BY MS. PAPANTONIO:
10 Q. So you don't know what that
11 means?
12 A. Other than the obvious of it
13 seems to be out of trend, no, I don't
14 specifically know that. I'm not an
15 analytical chemist.
16 Q. Okay. So the FDA is concluding
17 that out-of-trend results were retested
18 without an investigation due to greater
19 than a 1 percent differential in replicate
20 assay injections. Excuse me. And then we
21 see below that are valsartan batches,
22 right?
23 A. Yes, there are three valsartan
24 batches listed.

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1 Q. Do you know that there are C
2 batches listed?
3 A. Yes.
4 Q. Are you aware that C batches
5 are the old process?
6 A. Yes.
7 MS. NAGLE: Objection,
8 form.
9 BY MS. PAPANTONIO:
10 Q. And you also know that Torrent
11 used the old process, right?
12 A. Correct.
13 Q. And so these are potentially
14 batches that Torrent is getting from ZHP?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: I have no
18 idea whether Torrent received those
19 batches.
20 BY MS. PAPANTONIO:
21 Q. But the same company who is
22 telling you that Torrent products are okay
23 and not contaminated with NDMA are not
24 investigating out-of-trend results, were

Page 398

1 you aware of that?

2 MS. NAGLE: Objection,

3 form.

4 THE WITNESS: No.

5 BY MS. PAPANTONIO:

6 Q. If we look at A, we're talking

7 about -- excuse me, paragraph A, we're

8 talking about another valsartan batch,

9 right? And the last sentence tells us "Due

10 to this large differential, this batch of

11 valsartan was retested without conducting

12 an investigation and that passing results

13 were reported." Were you aware that ZHP

14 would retest its products and give it a

15 passing result without investigation?

16 MS. NAGLE: Objection,

17 form.

18 THE WITNESS: No, I was

19 not aware of that.

20 BY MS. PAPANTONIO:

21 Q. But this is the same company,

22 ZHP, that Torrent relied on for information

23 relating to the NDMA contamination, right?

24 MS. NAGLE: Objection,

Page 399

1 form.

2 THE WITNESS: Same, same

3 company, yes.

4 BY MS. PAPANTONIO:

5 Q. If you had learned this

6 information in 2017, would you have been

7 concerned?

8 MS. NAGLE: Objection,

9 form.

10 THE WITNESS: This

11 information is useful to know and

12 it is useful to investigate more

13 into the specific situations around

14 this. You know, it's hard to draw

15 conclusions from one batch and one

16 instance when things come from a

17 very large manufacturing plant like

18 this.

19 BY MS. PAPANTONIO:

20 Q. Right. But we can agree that

21 had Torrent audited ZHP at this time, they

22 would have found that ZHP does not

23 investigate out-of-trend results for its

24 valsartan, right?

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1 MS. NAGLE: Objection.

2 Form and foundation.

3 THE WITNESS: No,

4 there's no guarantee that we would

5 have seen these same things or

6 stumbled across similar, similar

7 items.

8 BY MS. PAPANTONIO:

9 Q. But we do know that they're

10 happening because the FDA is reporting them

11 in this investigation report, right?

12 MS. NAGLE: Objection,

13 form.

14 THE WITNESS: As I had

15 mentioned, I was not aware, I don't

16 remember seeing this report and I'm

17 not sure who within Torrent might

18 have or might not have been aware

19 of this.

20 BY MS. PAPANTONIO:

21 Q. Okay. Let's move onto page 16.

22 Looking at the last paragraph. Here the

23 FDA is concluding at ZHP that "Given the

24 firm's repeat assay testing due to

Page 401

1 variations among assay replicates, it is

2 unclear how the firm demonstrates the

3 validity of their own assay testing." Do

4 you see that?

5 A. Yes, I see that.

6 Q. So the FDA is concluding that

7 ZHP does not have valid testing; is that

8 correct?

9 MS. NAGLE: Objection,

10 form.

11 THE WITNESS: I don't

12 know that that's the conclusion

13 that they're drawing here.

14 BY MS. PAPANTONIO:

15 Q. Is it fair to say that Torrent

16 never figured out that ZHP doesn't

17 demonstrate validity in their testing,

18 because Torrent didn't have the ability to

19 test the product themselves?

20 MS. NAGLE: Objection.

21 Form and foundation.

22 THE WITNESS: I'm not

23 sure how those two things go

24 together. I'm sorry, I don't

Page 402

1 understand.
2 BY MS. PAPANTONIO:
3 Q. We can agree that throughout
4 this contamination period, Torrent was
5 relying on information from ZHP?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: Once we
9 became aware that there was a new
10 impurity, the information being
11 provided to us from ZHP was one of
12 the data sources that we were
13 utilizing to make decisions.
14 BY MS. PAPANTONIO:
15 Q. It was the only data source you
16 were utilizing to make decisions?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: No, that's
20 not true.
21 BY MS. PAPANTONIO:
22 Q. What other data were you
23 getting about the NDMA contamination?
24 A. We were also receiving

Page 403

1 information from FDA.
2 Q. All right. Let's look at F --
3 excuse me, page 23. Okay. This actually
4 is going to start on page 22, sorry. Okay.
5 Paragraph A at the bottom. Okay. Let's
6 look at this next-to-last sentence, where
7 the FDA inspector is saying "I attempted to
8 delineate the firm considers the initial
9 out-of-spec result invalid, but a passing
10 retest as valid. Upon inquiry with Mr. Li,
11 Mr. Jun Du clarified that that is a ghost
12 peak." Do you know what a ghost peak is?
13 A. No.
14 Q. He goes on to say "I indicated
15 that I am not familiar with this concept
16 and Mr. Du explained that this unknown peak
17 was causing the out of specification as a
18 ghost peak that appears from time to time
19 in chromatograms." Do you see that? "For
20 undetermined reasons," it goes on to say.
21 A. I see that.
22 Q. Are you aware that the
23 independent lab that determined NDMA was
24 present in valsartan tested one of these

Page 404

1 ghost peaks that ZHP is discussing and
2 found that the ghost peak was in fact NDMA?
3 Were you aware of that?
4 MS. NAGLE: Objection,
5 form.
6 THE WITNESS: No.
7 BY MS. PAPANTONIO:
8 Q. Are you aware that ZHP
9 recognized ghost peaks and simply ignored
10 them in their testing?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS: No.
14 BY MS. PAPANTONIO:
15 Q. Are you aware that the FDA
16 inspector warned ZHP that their actions
17 were wrong?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: No.
21 BY MS. PAPANTONIO:
22 Q. That the FDA told ZHP they
23 should not refer to these peaks as ghost
24 peaks, but rather they should investigate

Page 405

1 unknown peaks and identify them themselves?
2 MS. NAGLE: Objection,
3 form.
4 THE WITNESS: No.
5 BY MS. PAPANTONIO:
6 Q. Are you aware that had ZHP
7 identified one of these ghost peaks, they
8 would have found that it was NDMA in
9 valsartan?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: No.
13 BY MS. PAPANTONIO:
14 Q. Are you aware that had Torrent
15 tested the product and labeled one of these
16 ghost peaks, they would have found that
17 NDMA was present in valsartan?
18 MS. NAGLE: Objection,
19 form.
20 THE WITNESS: I'm sorry,
21 could you repeat that question?
22 BY MS. PAPANTONIO:
23 Q. Did you know that if Torrent
24 had identified one of these ghost peaks in

Page 406

1 the chromatogram, they would have learned
2 that it was actually the presence of NDMA?
3 MS. NAGLE: Same
4 objection.
5 THE WITNESS: I don't
6 know if Torrent was seeing these
7 ghost peaks.
8 BY MS. PAPANTONIO:
9 Q. Are you aware that your API
10 vendor, ZHP, continued to ignore these
11 ghost peaks even after the FDA inspector
12 issued them a warning?
13 MS. NAGLE: Objection,
14 form.
15 THE WITNESS: No.
16 BY MS. PAPANTONIO:
17 Q. And that that later led to the
18 recall of valsartan?
19 MS. NAGLE: Objection.
20 Form and foundation.
21 THE WITNESS: No.
22 BY MS. PAPANTONIO:
23 Q. Is this information that you
24 would have wanted to know at the time

Page 407

1 valsartan was being recalled?
2 A. I think all information is good
3 information, so it would have been useful
4 to know at that point.
5 Q. This certainly would have been
6 useful to know at the time Torrent was
7 deciding whether or not to keep their
8 product quarantined or release it, right?
9 MS. NAGLE: Objection,
10 form.
11 THE WITNESS: It would
12 have been another data point, yes.
13 BY MS. PAPANTONIO:
14 Q. And, again, Torrent had the
15 ability to audit ZHP with ZHP's permission,
16 right?
17 A. Yes.
18 MS. NAGLE: Objection,
19 form.
20 BY MS. PAPANTONIO:
21 Q. And had they audited ZHP in
22 2017, and found these same ghost peaks as
23 the FDA, Torrent could have found NDMA in
24 valsartan?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: As I
4 mentioned before, it's not a
5 forgone conclusion that we would
6 have seen the same information and
7 these ghost peaks had we audited.
8 BY MS. PAPANTONIO:
9 Q. But it's certainly possible,
10 right?
11 MS. NAGLE: Objection,
12 form.
13 THE WITNESS:
14 Theoretically.
15 BY MS. PAPANTONIO:
16 Q. And, Ms. Chitty, let me ask you
17 this, why didn't Torrent audit ZHP in the
18 two months it was deciding -- it was
19 determining whether NDMA was present in its
20 valsartan?
21 MS. NAGLE: Objection.
22 Form and foundation.
23 THE WITNESS: I don't
24 know.

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1 BY MS. PAPANTONIO:
2 Q. Do you believe it would have
3 been a good idea to investigate the
4 facility that Torrent is putting so much
5 trust in?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: Again,
9 that's not area of expertise, so
10 I'm not sure what is kind of
11 standard and expected in those
12 situations.
13 BY MS. PAPANTONIO:
14 Q. If you had the chance, would
15 you have advised Torrent India to
16 investigate ZHP's facilities?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: I'm not
20 sure, again, what necessarily value
21 that adds. It's good to inspect,
22 but it's not a guarantee. You only
23 see certain, you know, data at
24 certain points in time, so.

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1 BY MS. PAPANTONIO:
2 Q. And in this evaluation, the FDA
3 was able to see that ZHP ignores ghost
4 peaks on their chromatographs, right?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: That
8 appears to be what is discussed
9 here.
10 BY MS. PAPANTONIO:
11 Q. Okay. Now, to put this all
12 into context, this is 2017 that this
13 inspection is happening, right? Valsartan
14 is on the market?
15 A. Correct, Torrent valsartan
16 products are on the market.
17 Q. Torrent valsartan has been sold
18 on the market for years at this point?
19 MS. NAGLE: Objection,
20 form.
21 THE WITNESS: Again, I
22 don't recall exactly when it was
23 approved, but it is on the market
24 in 2017 for multiple products.

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1 BY MS. PAPANTONIO:
2 Q. Can you tell me how many
3 patients are relying on Torrent's valsartan
4 at this point in 2017?
5 MS. NAGLE: Objection.
6 Form and foundation.
7 THE WITNESS: No, I
8 don't know that information.
9 BY MS. PAPANTONIO:
10 Q. Can you tell me how many
11 valsartan pills Torrent is selling at the
12 time of this investigation?
13 MS. NAGLE: Objection.
14 Form and foundation.
15 THE WITNESS: No, I
16 don't know that information.
17 BY MS. PAPANTONIO:
18 Q. And you understand that this is
19 the FDA investigating one of Torrent's
20 vendors, ZHP, right?
21 A. It is FDA inspecting one of
22 Torrent's vendors, yes.
23 Q. So by the time the FDA has
24 conducted this investigation in 2017,

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1 Torrent has been relying on ZHP to supply
2 their API for years at this point?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: I don't
6 know when we started sourcing API
7 from ZHP.
8 BY MS. PAPANTONIO:
9 Q. But you do know you have been
10 sourcing ZHP API since at least 2014?
11 A. I don't recall specifically.
12 Again, as to when those products, when we
13 started sourcing API from this company.
14 Q. But you know you have been
15 sourcing ZHP API for, let's say, at least
16 four years?
17 A. I really can't quantify. I
18 don't know.
19 Q. Okay. But you do know patients
20 have been taking the drug for that long?
21 MS. NAGLE: Objection.
22 Form and foundation.
23 THE WITNESS: Again, I'm
24 not sure how long.

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1 BY MS. PAPANTONIO:
2 Q. Okay. But you do know that for
3 the period you're supplying Torrent's
4 valsartan ZHP API, patients are taking
5 that?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: As I said,
9 I don't know how long we had been
10 utilizing the ZHP API.
11 BY MS. PAPANTONIO:
12 Q. And, Ms. Chitty, do you
13 understand that it is not the FDA's job to
14 find problems with Torrent's vendors?
15 MS. NAGLE: Objection,
16 form.
17 THE WITNESS: Yeah, I
18 don't quite understand that
19 question, sorry.
20 BY MS. PAPANTONIO:
21 Q. As a finished dose
22 manufacturer, it is ultimately Torrent's
23 job to determine if there's problems
24 related to the production of its drug?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: We are
4 responsible for controlling the
5 quality of our products coming out
6 of our facilities, yes.
7 BY MS. PAPANTONIO:
8 Q. Right, so Torrent should be
9 able to find out that its own vendor, ZHP,
10 does not have integrity in their quality
11 control systems, right?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: Torrent,
15 you know, followed, as far as I
16 knew, the standard procedures for
17 vetting suppliers.
18 BY MS. PAPANTONIO:
19 Q. And we know that based on those
20 procedures, Torrent never found out that
21 ZHP does not have integrity in their
22 quality control system like we see in this
23 document?
24 MS. NAGLE: Objection to

Page 415

1 form.
2 THE WITNESS: Yeah, I'm
3 sorry, I got a little confused in
4 the question there. Can you repeat
5 that?
6 BY MS. PAPANTONIO:
7 Q. As far as you know, Torrent
8 never learned that its own vendor, ZHP,
9 lacks quality in ZHP's control system,
10 quality control system?
11 MS. NAGLE: Same
12 objection.
13 THE WITNESS: Again, I'm
14 not aware of what everyone within
15 Torrent knew regarding the
16 situation.
17 BY MS. PAPANTONIO:
18 Q. That information was never
19 communicated to you?
20 A. Not that I can remember, no.
21 Q. And like you said, you've
22 requested EIRs, inspection reports in the
23 past, but you never came across this ZHP
24 inspection report, right?

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1 A. I don't recall, no, ever seeing
2 this one specifically.
3 Q. So then you never learned that
4 your own vendor, ZHP, doesn't use science
5 when it tests the quality of its own API?
6 MS. NAGLE: Objection,
7 form.
8 THE WITNESS: Like I
9 said, I was not aware and it isn't
10 necessarily my responsibility to
11 seek out those things necessarily,
12 so.
13 BY MS. PAPANTONIO:
14 Q. And that's what I want to know,
15 whose job was it at Torrent to monitor this
16 vendor, ZHP? Whose job was it to find this
17 information?
18 MS. NAGLE: Objection.
19 Form and foundation.
20 THE WITNESS: And as
21 I've already mentioned, it's some
22 function of quality and the vendor
23 management system.
24

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1 BY MS. PAPANTONIO:
2 Q. So would that be Sushil
3 Jaiswal?
4 A. As I mentioned before, I don't
5 exactly remember where Sushil fits within
6 the groups at the plant. I don't know
7 exactly what his position was.
8 Q. We do know even if this did --
9 Torrent did have this information, it was
10 never communicated to you, right?
11 A. I don't recall receiving it.
12 Q. LP 1156. Can we actually do
13 1151 first? LP 1151.
14 Okay. I don't believe you're
15 on this email, Ms. Chitty, but let's start
16 from the second page.
17 MS. NAGLE: I'm sorry,
18 before you start asking questions,
19 Counsel, can we just get an exhibit
20 number?
21 MS. PENDLEY: LP --
22 Torrent 28, I'm sorry.
23 MS. NAGLE: Thank you.
24

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1 BY MS. PAPANTONIO:
2 Q. Okay. Starting on the second
3 page of that last email, do you know who
4 this Tarak is?
5 A. No, I don't recall who that is.
6 Q. Okay, some of these other names
7 are Torrent employees, though, right, Paras
8 or Sheth Paras and Shah Dhrumit?
9 A. I remember Paras. I'm not sure
10 about Mr. Shah.
11 Q. Okay. But we see the subject
12 line is "Valsartan notification - Torrent
13 India," right?
14 A. Correct.
15 Q. So this is a communication
16 between Torrent and ZHP?
17 A. It is definitely from --
18 involving Torrent, I'm not sure who these
19 other people are.
20 Q. Okay. If you just scroll out
21 real quick, we can see the ZHP logo up top.
22 Do you see that? The green little logo, it
23 says Hauhai Pharmaceutical.
24 A. Yeah. Is that an association

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1 with that email you were showing or --
2 Q. Yeah.
3 A. -- the one above it?
4 Q. Let's see. It's on the bottom
5 one, but okay, we'll just continue here.
6 It is -- well, this is Torrent
7 communicating with ZHP. So that's ZHP's
8 reply and we'll get to that.
9 So in this bottom email,
10 Torrent is asking for the analytical method
11 of residual solvents, GC, gas
12 chromatography testing, right? Do you see
13 that?
14 A. Yes.
15 Q. And they're also asking for
16 various information, like the latest three
17 batches of chromatograms and the relative
18 retention time of NDMA. So Torrent is
19 asking ZHP for information, right?
20 A. Yes.
21 Q. Information about NDMA?
22 A. Yes.
23 Q. And at this point on July 2,
24 2018, Torrent needs that information from

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1 ZHP because they don't have a testing
2 method of their own, right?
3 MS. NAGLE: Objection,
4 form.
5 THE WITNESS: Correct.
6 BY MS. PAPANTONIO:
7 Q. Okay. And let's see how ZHP
8 replies to Torrent in the next email.
9 Okay. Can we zoom in on the first email on
10 this page -- on this page, sorry. Okay.
11 So first we see it says "So, we thought it
12 is not necessary to provide a current
13 analytical method of residual solvents."
14 So ZHP is denying Torrent's request for a
15 test method at this point. Do you see
16 that?
17 MS. NAGLE: Objection,
18 form.
19 THE WITNESS: Yeah, I
20 believe that's what that says.
21 BY MS. PAPANTONIO:
22 Q. Okay. So at this point,
23 neither Torrent nor ZHP has the test method
24 for NDMA, right?

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1 MS. NAGLE: Objection.
2 Form and foundation.
3 THE WITNESS: I'm not
4 sure whether NDMA would be detected
5 under the residual solvents test
6 versus one of the other tests, so
7 no, I don't agree with that
8 conclusion.
9 BY MS. PAPANTONIO:
10 Q. Okay. But we do see that ZHP
11 signs this email with "PS: For better and
12 further communication, please kindly sign
13 the attached CDA as soon as possible."
14 A. I see that, yes.
15 Q. And then on the first page, we
16 see that the CDA they're referring to is a
17 nondisclosure agreement. Are you aware
18 that ZHP would only provide Torrent with
19 better and further information if Torrent
20 agreed to sign a nondisclosure agreement?
21 MS. NAGLE: Objection,
22 form.
23 THE WITNESS: No, I
24 don't recall being aware of this.

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1 BY MS. PAPANTONIO:
2 Q. In other words, in order for
3 Torrent to get information about the NDMA
4 or genotoxic impurity issue, Torrent was
5 required to sign this nondisclosure
6 agreement.
7 MS. NAGLE: Objection,
8 form.
9 BY MS. PAPANTONIO:
10 Q. Were you aware of that?
11 A. No.
12 Q. And then we see on the very
13 first email here Mr. Shah from Torrent
14 saying this is very critical and urgent.
15 Do you see that?
16 A. Yes.
17 Q. Okay. So let's take a look at
18 this confidential -- this confidentiality
19 agreement between ZHP and Torrent. And
20 just to be clear, as VP of science, you had
21 no idea this confidentiality agreement
22 existed?
23 A. Yeah, I'm not VP of science,
24 but I was not aware that this existed.

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1 Q. Okay. Let's take a look at
2 what it says. Oh, and this would be LP
3 1156 and it is marked as Torrent 29. Okay.
4 On the first page, it looks like an Indian
5 rupee, right, that's India's form of money,
6 right?
7 A. That is 100 rupees, yes.
8 Q. 100 rupees. Okay. And we can
9 see that the title of this is a
10 nondisclosure agreement. Do you see that?
11 A. Yes.
12 Q. And what is your understanding
13 of what a nondisclosure agreement is?
14 A. It's an agreement to define
15 what two parties feel are confidential
16 information and cannot be disclosed outside
17 of the relationship described here.
18 Q. Right. So we've got Torrent
19 Pharmaceuticals, Limited as the receiving
20 party and ZHP as the disclosing party. So
21 keeping that in mind, let's take a look at
22 what are the limitations of this agreement.
23 So turning to page 2, number, yeah, under
24 confidentiality, number two, we can see

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1 that ZHP defines confidentiality. Right
2 and they define it as "the existence or
3 contents of this agreement and the fact
4 that the disclosing party is investigating
5 the potential quality issue." Do you see
6 that?
7 A. No, sorry, I'm not.
8 Q. We're looking at 2.1, I'm
9 sorry, I should have directed better here.
10 2.1, "The parties acknowledge that the
11 disclosing party has provided --"
12 A. Okay.
13 Q. Okay. And then we're defining
14 what confidential information is here,
15 which is in bold, right? It says
16 "Confidential Information, orally, in
17 writing or intangible form, whether prior
18 to, on or after this date." And then it
19 says "For clarity, Confidential Information
20 also includes the existence of this
21 content -- of the contents of this
22 agreement," right? So what that means is
23 that you can't even talk about this
24 confidentiality agreement, right?

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1 MS. NAGLE: Objection.
2 Form and foundation.
3 THE WITNESS: Yeah, I'm
4 not really sure what that means,
5 sorry.
6 BY MS. PAPANTONIO:
7 Q. And you don't -- to be fair,
8 you never knew it existed, because no one
9 ever told you about it, right?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: Yeah, I
13 don't recall ever knowing of this.
14 BY MS. PAPANTONIO:
15 Q. And that's because by
16 definition, confidential information is the
17 existence of this agreement. Did you know
18 that?
19 A. No.
20 Q. It says Torrent also can't
21 disclose the fact that the disclosing party
22 is investigating a potential quality issue.
23 Did you know that?
24 A. No.

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1 Q. So as a regulatory agent, were
2 you aware that this is the only way that
3 ZHP agreed to give Torrent information on
4 this contamination?
5 MS. NAGLE: Objection,
6 form.
7 THE WITNESS: No.
8 BY MS. PAPANTONIO:
9 Q. As a regulatory agent, did you
10 know that that means that a customer --
11 excuse me, move to strike.
12 Were you aware that Torrent
13 couldn't even tell customers that there
14 might be a carcinogen in their medications
15 based on this confidential agreement?
16 MS. NAGLE: Objection,
17 form.
18 THE WITNESS: I wasn't
19 aware of the agreement.
20 BY MS. PAPANTONIO:
21 Q. That means that Torrent can't
22 tell doctors that prescribe the drug that
23 there's potentially a deadly carcinogen in
24 the valsartan Torrent API?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: I don't
4 really know the full implications
5 of the legal document, sorry.
6 BY MS. PAPANTONIO:
7 Q. Okay. Well, let's go down to
8 2.2 and then 2.2 tells us what is not
9 confidential information. It says
10 "Confidential Information shall not include
11 any of the following, any information which
12 the Receiving Party can demonstrate to the
13 Disclosing Party."
14 So under 2.2c, we see that
15 confidential information is not
16 confidential if "it is discovered
17 independently developed by the Receiving
18 Party or independent of any disclosures by
19 the Disclosing Party." So what that means
20 is that if Torrent had gotten independent
21 information about the NDMA contamination
22 from an independent lab, they could share
23 that with the public?
24 MS. NAGLE: Objection,

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1 form.
2 THE WITNESS: I'm sorry,
3 was that a question? I mean, that
4 was you explaining what was here,
5 but I don't know what the question
6 was.
7 BY MS. PAPANTONIO:
8 Q. Were you aware that Torrent
9 could share information about the
10 contamination if Torrent had gotten that
11 information from an independent source?
12 MS. NAGLE: Objection,
13 form.
14 THE WITNESS: No, I was
15 not aware of the subtleties related
16 to this agreement. Again, because
17 I didn't know about the agreement.
18 BY MS. PAPANTONIO:
19 Q. Right. You didn't know. And
20 let's talk about why you might not have
21 known about this agreement. Let's go to
22 2.3. It says "the Receiving Party shall
23 not disclose Confidential Information to
24 anyone other than its employees,

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1 consultants, agents or advisors thereby
2 known as Authorized Recipients to whom
3 shall -- to whom it shall disclose on a
4 need-to-know basis."
5 So if you did not know about
6 this confidentiality agreement, that means
7 you were not on a need-to-know basis at
8 Torrent. Would you agree with that
9 statement?
10 MS. NAGLE: Objection,
11 form.
12 THE WITNESS: I don't
13 know.
14 BY MS. PAPANTONIO:
15 Q. So as the person who
16 communicates with the FDA, provides
17 information, according to Torrent, is not a
18 need-to-know employee?
19 MS. NAGLE: Objection,
20 form.
21 BY MS. PAPANTONIO:
22 Q. Do you consider yourself an
23 employee who needs to know information
24 related to a carcinogen contamination?

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1 MS. NAGLE: Objection,
 2 form.
 3 THE WITNESS: I would
 4 believe that I do need to know
 5 about potential carcinogen
 6 contamination.
 7 BY MS. PAPANTONIO:
 8 Q. Are you aware that your company
 9 didn't believe that you needed to know this
 10 information as VP of science and strategy?
 11 MS. NAGLE: Objection,
 12 form.
 13 THE WITNESS: Again, as
 14 I stated, I was not aware of any of
 15 this.
 16 BY MS. PAPANTONIO:
 17 Q. Okay. And then if we go to
 18 number three. If we look at 3.1, this is
 19 kind of a long sentence, but I'll try to
 20 break it down. It says "The Receiving
 21 Party," which is Torrent, "shall use the
 22 Confidential Information only for the
 23 purpose of fulfilling its regulatory
 24 obligations in the relevant territory,

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1 provided that (a) such obligations are
 2 mandatorily required by applicable laws."
 3 So that means that Torrent has to share
 4 information that's mandatory to things like
 5 the U.S. government or the FDA, right?
 6 Would you agree with that?
 7 MS. NAGLE: Objection to
 8 form.
 9 THE WITNESS: That's --
 10 that's your interpretation. I
 11 don't know. I'm not a lawyer here,
 12 so, sorry.
 13 BY MS. PAPANTONIO:
 14 Q. No, I understand. All right.
 15 And then it says "(b) the Receiving Party
 16 shall use reasonable efforts to minimize
 17 the scope of disclosure." So as you sit
 18 here, do you understand that Torrent is
 19 taking every step it can to minimize
 20 disclosure about this contamination?
 21 MS. NAGLE: Objection,
 22 form.
 23 THE WITNESS: No, I'm
 24 not aware of steps to minimize

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1 disclosure.
 2 BY MS. PAPANTONIO:
 3 Q. Okay. And then let's look at
 4 3.3. "The Disclosing Party," which is ZHP
 5 in this case, "has not made and will not
 6 make any express or implied representations
 7 or warranty in this agreement as to the
 8 accuracy or completeness of the
 9 Confidential Information." This is ZHP
 10 telling Torrent that the information we
 11 give you might not be accurate. And we now
 12 know, right, the information ZHP was not in
 13 fact accurate and you know that?
 14 MS. NAGLE: Objection to
 15 form.
 16 THE WITNESS: I'm sorry,
 17 your question is that we were aware
 18 that information was not accurate?
 19 BY MS. PAPANTONIO:
 20 Q. Does it surprise you to know
 21 that Torrent entered into an agreement with
 22 ZHP where ZHP asserted that they did not
 23 have to give accurate information to
 24 Torrent?

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1 MS. NAGLE: Objection to
 2 form.
 3 THE WITNESS: I really
 4 have no context or background to
 5 understand what is standard in a
 6 confidentiality agreement, sorry.
 7 BY MS. PAPANTONIO:
 8 Q. Okay. And then I just want to
 9 go to the final page just show you that
 10 this agreement was signed. Okay. Do you
 11 see -- do you know who this Chandrasekhar
 12 is at the bottom here, vice president of
 13 procurement signed it?
 14 A. I think that's the person in
 15 previous emails. He's referred to as
 16 Chakar, so yes, I'm familiar with that
 17 person.
 18 Q. All right. And then we have
 19 the vice president of finance who signs
 20 this. Now, knowing this information,
 21 Ms. Chitty, does it surprise you to hear
 22 that Torrent was withholding information
 23 related to the contamination from the
 24 public?

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1 MS. NAGLE: Objection,
2 form.
3 THE WITNESS: I don't
4 know that Torrent was withholding
5 information from the public.
6 BY MS. PAPANTONIO:
7 Q. Does it surprise you to see
8 this confidentiality agreement between
9 Torrent and ZHP?
10 A. Again, it's not part of my
11 normal business or area of expertise. I
12 don't know what's normal or common. I just
13 wasn't aware of this.
14 MS. PAPANTONIO: Okay.
15 One second. All right. We're
16 going to take a break, ten minutes.
17 THE VIDEOGRAPHER: It's
18 6:01, we are off the video record.
19 - - - - -
20 (A recess was taken at this time.)
21 - - - - -
22 THE VIDEOGRAPHER: 6:13,
23 we are on the video record.
24

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1 MS. PAPANTONIO: All
2 right. Ms. Chitty, I want to thank
3 you so much for your time. We
4 really appreciate you coming here
5 today and that is all the questions
6 that we have.
7 THE WITNESS: Okay.
8 MS. PAPANTONIO: We can
9 go off the record.
10 MS. NAGLE: I have a few
11 quick questions.
12 MS. PAPANTONIO: Okay.
13 Back on the record we go.
14 MS. NAGLE: Are we still
15 on the record?
16 THE VIDEOGRAPHER: We
17 are.
18 BY MS. NAGLE:
19 Q. Okay. Great. So, Ms. Chitty,
20 you were asked a couple of times today
21 about why Torrent didn't act or recall when
22 you were notified there was an issue with
23 the new process for the API. Why, why
24 didn't you guys also, you know, start

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1 immediately testing the old process?
2 A. So the first notification that
3 we had received in June, as you said, it
4 was about the new process and a potential
5 unknown impurity. An impurity profile of a
6 drug is very specific to the way that it's
7 made. Because these two routes of
8 synthesis are different, it's not inherent
9 that an impurity you see with one route of
10 synthesis you will see with a second.
11 Q. And I think you were also asked
12 by counsel, you know, why not, you know,
13 quarantine old process just to be sure.
14 Can you explain what little bit, you know,
15 why you wouldn't quarantine or take a drug
16 off market?
17 A. Yeah, as I mentioned, when we
18 were talking about that, you don't recall a
19 product without firm data in hand. These
20 products, as we've talked about multiple
21 times today, are for people with high blood
22 pressure. And so it's critical that they
23 have the ability to get this medication and
24 potentially also harmful if there's not

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1 product on the market and shortages and
2 things like that that an unnecessary recall
3 can lead to.
4 MS. NAGLE: Nothing
5 further.
6 THE VIDEOGRAPHER: Okay.
7 Off the video record then?
8 6:16 p.m., we are off the video
9 record. This concludes the video
10 deposition of Dawn Chitty.
11 - - - - -
12 (Whereupon, the deposition was
13 concluded at 6:16 p.m.)
14 - - - - -
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<p style="text-align: right;">Page 438</p> <p>1 CERTIFICATION</p> <p>2</p> <p>3</p> <p>4 I HEREBY CERTIFY that the proceedings and</p> <p>5 evidence are contained fully and accurately in the</p> <p>6 stenographic notes taken by me upon the foregoing</p> <p>7 matter on May 13, 2021, and that this is a correct</p> <p>8 transcript of same.</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15 _____</p> <p>16 Robin L. Clark</p> <p>17 Registered Professional Reporter</p> <p>18</p> <p>19</p> <p>20</p> <p>21 (The foregoing certification of this</p> <p>22 transcript does not apply to any reproduction of the</p> <p>23 same by any means unless under the direct control</p> <p>24 and/or supervision of the certifying reporter.)</p> <p style="text-align: right;">Page 439</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over carefully</p> <p>4 and make any necessary corrections.</p> <p>5 You should state the reason in the appropriate</p> <p>6 space on the errata sheet for any corrections</p> <p>7 that are made.</p> <p>8 After doing so, please sign the errata</p> <p>9 sheet and date it.</p> <p>10 You are signing same subject to the</p> <p>11 changes you have noted on the errata sheet,</p> <p>12 which will be attached to your deposition.</p> <p>13 It is imperative that you return the</p> <p>14 original errata sheet to the deposing attorney</p> <p>15 within thirty (30) days of receipt of the deposition</p> <p>16 transcript by you. If you fail to do so, the</p> <p>17 deposition transcript may be deemed to be accurate</p> <p>18 and may be used in court.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 440</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p style="text-align: right;">Page 441</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, DAWN CHITTY, do hereby</p> <p>4 certify that I have read the foregoing pages</p> <p>5 and that the same is a correct</p> <p>6 transcription of the answers given by me to</p> <p>7 the questions therein propounded, except for</p> <p>8 the corrections or changes in form or</p> <p>9 substance, if any, noted in the attached</p> <p>10 Errata Sheet.</p> <p>11 _____ DATE</p> <p>12 DAWN CHITTY</p> <p>13 Subscribed and sworn to before me this</p> <p>14 day of _____,</p> <p>15 2021.</p> <p>16 My commission expires:</p> <p>17</p> <p>18</p> <p>19</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
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Exhibit 96

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
2 CAMDEN VICINAGE

— — —

IN RE: VALSARTAN, : MDL NO. 2875
 LOSARTAN, AND :
 IRBESARTAN PRODUCTS : CIVIL NO.
 LIABILITY LITIGATION : 19-2875
 : (RBK/JS)

THIS DOCUMENT APPLIES : HON. ROBERT
7 TO ALL CASES : B. KUGLER
8 - CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

VOLUME I

— — —

June 4, 2021

— — —

Videotaped remote deposition of SUSHIL JAISWAL, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 3:32 p.m., India Standard Time, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

1 GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
2 deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 ZOOM APPEARANCES:</p> <p>2</p> <p>3 LEVIN PAPANTONIO RAFFERTY PROCTOR</p> <p>4 BUCHANAN, O'BRIEN, BARR, MOUGEY, PA</p> <p>5 BY: MADELINE PENDLEY, ESQ.</p> <p>6 DANIEL NIGH, ESQ.</p> <p>7 SARA PAPANTONIO, ESQ.</p> <p>8 316 South Baylen Street, Suite 600</p> <p>9 Pensacola, Florida 32502</p> <p>10 (888) 435-7001</p> <p>11 mpendley@levinlaw.com</p> <p>12 dnigh@levinlaw.com</p> <p>13 spapantonio@levinlaw.com</p> <p>14 Representing the Plaintiffs</p> <p>15</p> <p>16 PRETI FLAHERTY, LLP</p> <p>17 BY: JOHN J. CRONAN, III, ESQ.</p> <p>18 One City Center</p> <p>19 Portland, Maine 04101</p> <p>20 (207) 791-3000</p> <p>21 jcronan@preti.com</p> <p>22 Representing the Plaintiffs</p> <p>23</p> <p>24 WAGNER REESE, LLP</p> <p>25 BY: JEFF GIBSON, ESQ.</p> <p>26 201 N. Illinois Street</p> <p>27 16th Floor – South Tower</p> <p>28 Indianapolis, Indiana 46204</p> <p>29 (866) 957-6614</p> <p>30 Jgibson@wagnerreese.com</p> <p>31 Representing the Plaintiffs</p> <p>32</p> <p>33 THE LAW OFFICES OF GEORGE A. BARTON, P.C.</p> <p>34 BY: STACY A. BURROWS, ESQ.</p> <p>35 7227 Metcalf Avenue</p> <p>36 Suite 301</p> <p>37 Overland Park, Kansas 66204</p> <p>38 (913) 563-6253</p> <p>39 stacy@georgebartonlaw.com</p> <p>40 Representing the Plaintiffs</p> <p>41</p> <p>42</p>	<p style="text-align: right;">Page 4</p> <p>1 ZOOM APPEARANCES: (Cont'd.)</p> <p>2</p> <p>3 CIPRIANI & WERNER, P.C.</p> <p>4 BY: AMANDA RUGGIERI, ESQ.</p> <p>5 450 Sentry Parkway, Suite 200</p> <p>6 Blue Bell, Pennsylvania 19422</p> <p>7 (610) 567-0700</p> <p>8 Aruggieri@c-wlaw.com</p> <p>9 Representing the Defendant, Aurobindo</p> <p>10 Pharma, USA, Inc. and Aurolife Pharma,</p> <p>11 LLC</p> <p>12</p> <p>13 ALSO PRESENT:</p> <p>14</p> <p>15 VIDEOTAPE TECHNICIAN:</p> <p>16 Ray Moore</p> <p>17</p> <p>18 LITIGATION TECHNICIAN:</p> <p>19 Jeff Martin</p> <p>20</p> <p>21 Lauren Massey - Paralegal</p> <p>22 (Levin Papantonio)</p> <p>23 Nidhi Mehta</p> <p>24 (Torrent)</p> <p>25</p> <p>26 Vidhi Kotak</p> <p>27 (Torrent)</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p>
<p style="text-align: right;">Page 3</p> <p>1 ZOOM APPEARANCES: (Cont'd.)</p> <p>2</p> <p>3 KIRKLAND & ELLIS, LLP</p> <p>4 BY: ALEXIA RENEE BRANCATO, ESQ.</p> <p>5 BRITTNEY NAGLE, ESQ.</p> <p>6 601 Lexington Avenue</p> <p>7 New York, New York 10022</p> <p>8 (212) 909-3334</p> <p>9 alexia.brancato@kirkland.com</p> <p>10 brittney.nagle@kirkland.com</p> <p>11 Representing the Defendant, Torrent</p> <p>12 Pharmaceuticals</p> <p>13</p> <p>14 DUANE MORRIS, LLP</p> <p>15 BY: KELLY A. BONNER, ESQ.</p> <p>16 30 South 17th Street</p> <p>17 Philadelphia, PA 19103</p> <p>18 (215) 979-1158</p> <p>19 kabonner@duanemorris.com</p> <p>20 Representing the Defendants, Zhejiang</p> <p>21 Huahai Pharmaceutical Co. Ltd., Prinston</p> <p>22 Pharmaceutical Inc., Huahai U.S., Inc.,</p> <p>23 and Solco Healthcare US, LLC</p> <p>24</p> <p>25 GREENBERG TRAURIG, LLP</p> <p>26 BY: GEROND J. LAWRENCE, ESQ.</p> <p>27 Terminus 200</p> <p>28 3333 Piedmont Road, NE</p> <p>29 Suite 2500</p> <p>30 Atlanta, Georgia 30305</p> <p>31 (678) 553-2287</p> <p>32 Lawrencenge@gtlaw.com</p> <p>33 Representing the Defendants, Teva</p> <p>34 Pharmaceutical Industries, Ltd., Teva</p> <p>35 Pharmaceuticals USA, Inc., Actavis LLC,</p> <p>36 and Actavis Pharma, Inc.</p> <p>37</p> <p>38</p> <p>39</p> <p>40</p>	<p style="text-align: right;">Page 5</p> <p>1</p> <p>2 I N D E X</p> <p>3</p> <p>4</p> <p>5 Testimony of:</p> <p>6 SUSHIL JAISWAL, Ph.D.</p> <p>7</p> <p>8 By Ms. Pendley 11</p> <p>9</p> <p>10 By Mr. Nigh 283</p> <p>11</p> <p>12</p> <p>13 E X H I B I T S</p> <p>14</p> <p>15</p> <p>16 NO. DESCRIPTION PAGE</p> <p>17 Torrent-214 LinkedIn resume of Sushil Jaiswal 13</p> <p>18</p> <p>19 Torrent-215 Curriculum vitae of Sushil Jaiswal 18</p> <p>20 Torrent-216 TORRENT-MDL2875 -00181466 25</p> <p>21 Site Master File</p> <p>22 Formulation</p> <p>23</p> <p>24 Torrent-217 TORRENT-MDL2875 -00523103 55</p> <p>25 EMA CHMP Guideline</p> <p>26 On the limits of</p> <p>27 Genotoxic Impurities</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p>

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<p style="text-align: right;">Page 10</p> <p style="text-align: center;">- - - DEPOSITION SUPPORT INDEX - - -</p> <p>Direction to Witness Not to Answer PAGE LINE None.</p> <p>Request for Production of Documents PAGE LINE None.</p> <p>Stipulations PAGE LINE None.</p> <p>Questions Marked PAGE LINE 250 16</p>	<p style="text-align: right;">Page 12</p> <p>A. Good afternoon.</p> <p>Q. Have you ever been deposed before?</p> <p>A. Can you repeat, ma'am.</p> <p>Q. Yes. Have you ever been deposed before?</p> <p>A. No. This is first time.</p> <p>Q. Okay. So I'll go over some of the kind of ground rules with you to make sure we're on the same page. So basically all we're going to be doing is asking you some questions.</p> <p>And as you saw there's a court reporter here today. So she's going typing out everything I say and everything you say.</p> <p>So it's really important that we don't interrupt each other. So let me get my full question out before you respond, and I'll let you answer as well. Okay?</p> <p>A. Sure.</p> <p>Q. Okay. And also, be sure to give verbal responses, you know, an</p>
<p style="text-align: right;">Page 11</p> <p style="text-align: center;">- - -</p> <p>THE VIDEOGRAPHER: We are now on the record.</p> <p>Today's date is June 4th, and the time is approximately 6:02 a.m. (3:32 p.m. India Standard Time.)</p> <p>This begins the deposition of Sushil Jaiswal in the matter of Valsartan, Irbesartan Products Liability Litigation.</p> <p>Counsel will be noted on the stenographic record.</p> <p>Will the court reporter please swear in the witness.</p> <p style="text-align: center;">- - -</p> <p>... SUSHIL JAISWAL, Ph.D., having been first duly sworn, was examined and testified as follows:</p> <p style="text-align: center;">- - -</p> <p>EXAMINATION</p> <p style="text-align: center;">- - -</p> <p>BY MS. PENDLEY:</p> <p>Q. Good afternoon, Mr. Jaiswal.</p>	<p style="text-align: right;">Page 13</p> <p>actual "yes," or "no," something that she can actually put on the record. You can't just nod or shake your head. Does that make sense?</p> <p>A. Yes.</p> <p>Q. All right. And do you understand that you're under oath here today?</p> <p>A. Yes.</p> <p>Q. The last thing is, if your attorney objects, you know, she'll say something like "objection." Let her get through the objection, but you can still answer the question. Okay?</p> <p>A. Okay.</p> <p>Q. All right.</p> <p>MS. PENDLEY: So I want to pull up LP 25.</p> <p>(Document marked for identification as Exhibit Torrent-214.)</p> <p>BY MS. PENDLEY:</p> <p>Q. We're going to take a look at your deposition notice, okay.</p>

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1 MS. PENDLEY: This is going
2 to be marked Torrent Exhibit 214.
3 BY MS. PENDLEY:
4 Q. Mr. Jaiswal, have you seen
5 this before?
6 A. No.
7 Q. I want to direct you to
8 Page 5, if you would. It lists out some
9 topics that we're going to discuss today.
10 So as you can see these topics are about
11 testing valsartan API and finished dose.
12 Are you prepared to talk
13 about topics like this today?
14 A. Yeah, I'm prepared for this.
15 Q. Okay. If you go to the next
16 page, you can see topics about quality
17 assurance and quality control activities.
18 Are you prepared to talk
19 about these?
20 A. Yes, I'm prepared.
21 Q. Okay. And then the last one
22 is about process development, changes to
23 manufacturing process of valsartan API.
24 Are you prepared to talk

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1 about this today?
2 A. Yes.
3 MS. PENDLEY: We can take
4 this exhibit down.
5 BY MS. PENDLEY:
6 Q. Okay. Mr. Jaiswal how long
7 did you prepare for this deposition
8 today?
9 A. Maybe since last week or so.
10 Q. Okay. Did you review any
11 documents to prepare for your deposition?
12 A. Not really that much, but I
13 tried to recollect, thinking what had
14 been happened in the last two years about
15 this history that started since 2018.
16 And it was helpful in meeting, like what
17 kind of data being discussed that is
18 being investigated.
19 Q. Okay. About how much time
20 did you spend meeting with your
21 attorneys?
22 A. I'm not quite understanding
23 your question.
24 Q. Okay. How much time did you

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1 spend meeting with your attorneys?
2 A. Okay. I had three sessions
3 with my attorneys. And it's meeting from
4 almost -- from four hour to six hours.
5 Q. Four to six hours each time
6 or total?
7 THE WITNESS: IT, can you
8 see that?
9 Just a moment. I need IT, a
10 lot of people happening in here.
11 MS. PENDLEY: No problem.
12 Can we go off the record.
13 THE VIDEOGRAPHER: The time
14 is now 6:07 a.m. (3:38 p.m. India
15 Time). We're going off the
16 record.
17 (Brief pause.)
18 THE VIDEOGRAPHER: The time
19 is now 6:08 a.m. (3:38 p.m. India
20 Time). We're back on the record.
21 BY MS. PENDLEY:
22 Q. So you just told me that you
23 met with your attorneys for four to
24 six hours. Was that for each of the

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1 three sessions or was that four to
2 six hours total?
3 A. No, it's for each session.
4 Q. Okay. Sounds good. Who
5 other than your attorneys did you meet
6 with to prepare for today?
7 A. Apart from that, definitely
8 a few of my team members, with whom I
9 discussed what has happened in the last
10 two years, those things had been
11 discussed, few of the team member.
12 Q. Okay. Who did you meet
13 with? Do you remember?
14 A. Oh yes. One is Maitrayee
15 Mukherji and Kalpesh Patel and Tripti
16 Ghandi and Priti Shah. They were the
17 four of them.
18 Q. Did you guys exchange
19 e-mails as well?
20 A. Because of this deposition?
21 Q. Yes.
22 A. Yes, I think one or two
23 e-mail. Not related to the information.
24 But to tell them that we wanted to meet

<p style="text-align: right;">Page 18</p> <p>1 for this discussion, that kind mail. 2 Q. All right. So I want to 3 switch gears a little bit. Let's look at 4 LP 1527. 5 (Document marked for 6 identification as Exhibit 7 Torrent-215.) 8 MS. PENDLEY: This will be 9 marked as Torrent Exhibit 215. 10 MS. BRANCATO: Sorry, 11 Madeline, I don't mean to 12 interrupt you. But last time you 13 put an exhibit up, there was 14 nothing in the chat or in the 15 link. 16 Are you planning on putting 17 them there for us to download? 18 MS. PENDLEY: The trial tech 19 should be doing it. 20 MS. BRANCATO: Okay. 21 There's nothing yet. 22 TRIAL TECH: Yeah, hold on, 23 I'll get it. 24 MS. PENDLEY: Thanks, Jeff.</p>	<p style="text-align: right;">Page 20</p> <p>1 record. 2 (Brief pause.) 3 THE VIDEOGRAPHER: The time 4 is now 6:13 a.m. (3:43 p.m. India 5 Time). We're back on the record. 6 BY MS. PENDLEY: 7 Q. Okay. Mr. Jaiswal, can you 8 see the document now? 9 A. Yes. 10 Q. Okay. And you mentioned 11 this is your CV, right? 12 A. Yeah. 13 Q. Is this your most up-to-date 14 CV? 15 A. Yes. 16 Q. I want to look at Page 3. 17 Top of Page 3 here it says that you used 18 to work for Torrent Pharmaceuticals in 19 1996 and 1997. 20 Do you see that? 21 A. Yeah. 22 Q. Okay. What was your job 23 back when you initially worked at Torrent 24 back in 1996?</p>
<p style="text-align: right;">Page 19</p> <p>1 THE WITNESS: By going to 2 the chat box, this is requiring 3 login information. 4 MS. BRANCATO: It's not the 5 link that's in the chat, Sushil. 6 Here. I'll put the exhibit link 7 or Jeff, would you mind putting 8 the right exhibit link into the 9 chat so Sushil can navigate, 10 please. 11 Sushil, do you see two 12 documents in the chat now? The 13 first document is the one you want 14 to look at right now. 15 THE WITNESS: Actually, by 16 opening the chat box -- just a 17 moment. 18 I think I need to take IT 19 help here. 20 MS. PENDLEY: Let's go off 21 the record for just a second. 22 THE VIDEOGRAPHER: The time 23 is now 6:12 a.m. (3:42 p.m. India 24 Time). We're going off the</p>	<p style="text-align: right;">Page 21</p> <p>1 A. During this period I joined 2 this company as an executive. And I was 3 in a PC lab. That is known as a process 4 control laboratory. And I was doing a 5 kind of like small scale laboratory 6 trials for some of the product groups. 7 Q. Okay. Why did you leave 8 Torrent in '97? 9 A. Yeah, this is what is my 10 responsibilities. And then I worked 11 almost for one year in that position. 12 And I left and joined some other 13 operation. 14 Q. Okay. Let's go to Page 2. 15 We're kind of working backwards here up 16 towards the front. 17 Okay. We can see that you 18 worked at another company for a while. 19 And then you worked at Aurobindo. 20 A. Yeah. 21 Q. And then you worked at 22 Macleods Pharmaceuticals, right? 23 A. Yes. 24 Q. And your position at</p>

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1 Macleods was the vice president,
2 executive vice president, is that right?
3 A. Say while leaving that
4 organization, I was president of
5 the organization. And then I resigned
6 from there and I joined Torrent.
7 Q. All right. Why did you want
8 to resign from Macleods Pharmaceuticals?
9 A. Pardon?
10 Q. Why did you resign from
11 Macleods?
12 A. Okay. Basically a location
13 preference. I wanted move out of Mumbai
14 and definitely a better job profile.
15 Q. Okay.
16 A. To be able leave and sign up
17 to Torrent.
18 Q. Okay. And then you worked
19 at Torrent Pharmaceuticals Limited since
20 July 2017 to present, right?
21 A. Yeah.
22 Q. Okay. And Torrent
23 Pharmaceuticals Limited, that is Torrent
24 that's in India; is that right?

Page 23

1 A. Yes, it's India.
2 Q. And then Torrent has, I
3 don't know if the right term is branch or
4 division in the U.S. as well, right?
5 A. Yes, that's correct.
6 Q. So in your role as executive
7 directors of quality as listed on this
8 CV, do you communicate with Torrent U.S.?
9 A. Yes, I do communicate with
10 the U.S. team.
11 Q. Okay. Do you communicate
12 directly with the FDA?
13 A. No, not with FDA. Because
14 for that we have a U.S. rep and they do.
15 Q. Okay. So if Torrent India
16 wants to get information to the FDA, they
17 give it to Torrent's U.S. agent, and they
18 pass it along; is that right?
19 A. Yeah.
20 Q. Okay. So right above this
21 chart where you list out where you work,
22 you see the last kind of bullet point
23 that's marked with a check. "Management
24 of reference standard, working standard,

Page 24

1 and characterization of impurities."
2 Do you see that?
3 A. Yeah.
4 Q. Okay. So you have
5 experience in identifying impurities in
6 pharmaceuticals; is that fair?
7 A. The meaning of this is that
8 the pharmaceutical analysis requires a
9 standardization of the working standard.
10 And the known impurities are standards
11 which is to be used in the analysis.
12 This is for that reference.
13 Q. Have you published any
14 studies -- actually, have you a study
15 about anything before?
16 A. So during my Ph.D. I did
17 some research work and it has been
18 published.
19 Q. Okay. Have you published
20 any studies about identifying genotoxic
21 impurities in pharmaceuticals?
22 A. No.
23 MS. PENDLEY: I want to look
24 at LP 196. This will be marked as

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1 Torrent Exhibit 216.
2 (Document marked for
3 identification as Exhibit
4 Torrent-216.)
5 THE WITNESS: 1396?
6 MS. PENDLEY: Yes.
7 (Whereupon, a discussion was
8 held off the stenographic record.)
9 MS. PENDLEY: If we can pull
10 up LP 1396 whenever we get
11 situated. All right. If we can
12 go to the next page.
13 BY MS. PENDLEY:
14 Q. Mr. Jaiswal, you let me know
15 when you can see this on your end. It
16 should be on your screen in Zoom. If you
17 want to pull it up in the chat room.
18 A. Yeah, I can see this.
19 Q. For the record this is
20 TORRENT-MDL2875-00181466.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

<p>Page 26</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>Page 27</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>

Page 30

[REDACTED]

Page 32

1 Q. Okay. Mr. Jaiswal, you
2 understand that we're here today because
3 Torrent's valsartan product was
4 contaminated with nitrosamines, right?
5 A. Can you repeat that
6 question?
7 Q. Yeah. You understand that
8 we are here today to talk about Torrent's
9 valsartan product being contaminated with
10 nitrosamines, right?
11 A. So we are here to discuss
12 that -- this topic.
13 Q. Okay.
14 A. Yes, I'm aware.
15 Q. And you understand that
16 those nitrosamines specifically were NDMA
17 and NDEA, right?
18 A. Yeah.
19 Q. So how were you personally
20 notified of the contamination? Do you
21 remember?
22 A. Yes. In fact, we got a
23 communication from committee. And they
24 notified us that they basically got a

Page 31

[REDACTED]

21 MS. PENDLEY: Okay. All
22 right. You can take this one
23 down.
24 BY MS. PENDLEY:

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1 notification from our API supplier.
2 Q. Okay. And your API supplier
3 was ZHP; is that correct?
4 A. Yes, ZHP.
5 MS. PENDLEY: Okay. I want
6 to look at LP 1102.
7 For the record this has been
8 previously marked as Torrent
9 Exhibit 2.
10 THE WITNESS: This is file
11 1102?
12 MS. PENDLEY: Yes.
13 (Document previously marked
14 for identification as Exhibit
15 Torrent-2.)
16 BY MS. PENDLEY:
17 Q. Do you see the cover page in
18 the document?
19 A. Yes.
20 Q. All right. We can see, if
21 you look at the bottom of the page, this
22 is a document that's published by the
23 World Health Organization in 2002.
24 Do you see that?

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1 A. Yeah.
2 Q. And we see the document is
3 called n-nitrosodimethylamine.
4 That's NDMA, right?
5 A. Mm-hmm.
6 Q. Is that a yes? I'm sorry.
7 A. Yes.
8 Q. Okay. Have you ever seen
9 this document before?
10 A. No.
11 Q. All right. I want to walk
12 you through a couple of things. If we
13 can go to Page 4.
14 A. Page 4?
15 Q. Yep. And they're marked at
16 the bottom. It will be the actual number
17 4, not Roman Numeral IV.
18 A. Yeah. I'm on Page 4.
19 Q. Okay. If you could look at,
20 there's a bunch of information on this
21 page. I want to focus on the right-hand
22 side, third paragraph down. It says,
23 "Based upon laboratory studies in which
24 tumors have been induced in all species

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1 examined at relatively low doses, NDMA is
2 clearly carcinogenic."
3 Do you see that?
4 A. If you referring to Page 4,
5 I'm not -- Page 4 is on here -- just a
6 moment.
7 Q. Okay.
8 A. Just a moment. Yeah, I'm on
9 Page 4 now.
10 Q. All right. Looking at that
11 paragraph, it says, "Based upon
12 laboratory studies in which tumors have
13 been induced in all species examined at
14 relatively low doses, NDMA is clearly
15 carcinogenic."
16 Are you with me?
17 A. Yes, reading here.
18 Q. Yes. So what does
19 carcinogenic mean?
20 A. Carcinogenic is like a
21 definition of the compound that leads to
22 carcinogenicity.
23 Q. Okay. Does that mean it can
24 cause cancer?

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1 A. I'm not really sure.
2 Q. Okay. Can we agree that the
3 word carcinogenic means can cause cancer,
4 yes or no?
5 A. See, it all depends upon at
6 what level, what is the potency, what is
7 the dose. There are so many factors
8 there that a compound, if it is being
9 categorized into this category, is not
10 ultimately is being -- causing a cancer.
11 It has a lot of other
12 related topics and internal analysis that
13 is not known. We cannot be claiming that
14 as basically causing a cancer.
15 Q. Okay. I understand what
16 you're saying. Can we agree that the
17 word "carcinogenic" means can cause
18 cancer?
19 A. Yeah. That is true. I
20 agree with that.
21 Q. All right. Let's look at
22 the bottom of this paragraph where it
23 says, "Qualitatively the metabolism of
24 NDMA appears to be similar in humans and

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1 animals. As a result it is considered
2 highly likely that NDMA is carcinogenic
3 to humans, potentially at relatively low
4 levels of exposure."
5 Do you see that?
6 A. Yeah, I read that.
7 Q. So this sentence says, NDMA
8 can cause cancer to humans.
9 Do you agree with that?
10 MS. BRANCATO: Objection to
11 form and foundation. Outside the
12 scope.
13 THE WITNESS: So it's
14 definitely -- I never gone through
15 this report. I never participated
16 in this kind of studies, or what
17 kind of studies it is.
18 But definitely based upon
19 that limitation, I cannot comment
20 on that. This is technical.
21 BY MS. PENDLEY:
22 Q. Okay. Just taking the
23 document for what it says, can we agree
24 that this document says NDMA can cause

<p>Page 38</p> <p>1 cancer to humans?</p> <p>2 MS. BRANCATO: Same</p> <p>3 objections.</p> <p>4 THE WITNESS: This is what</p> <p>5 I'm indicating. That document,</p> <p>6 yes, I'm able to read it. But I'm</p> <p>7 not able to comment on it whether</p> <p>8 it is right or wrong, because I'm</p> <p>9 not the right person, because I</p> <p>10 wouldn't know the studies being</p> <p>11 done, what is involved, and that's</p> <p>12 why I'm not able to comment on</p> <p>13 that aspect.</p> <p>14 BY MS. PENDLEY:</p> <p>15 Q. One second. Mr. Jaiswal,</p> <p>16 I'm looking at your 30(b)(6) notice. And</p> <p>17 one of your topics that you told me that</p> <p>18 you were prepared to discuss today is,</p> <p>19 "Torrent's evaluation and knowledge of</p> <p>20 the health risks of nitrosamines,</p> <p>21 including NDMA and NDEA."</p> <p>22 A. Yeah.</p> <p>23 Q. So I'm asking you today</p> <p>24 about the health risks of NDMA in this</p>	<p>Page 40</p> <p>1 Organization document on NDMA?</p> <p>2 A. No.</p> <p>3 Q. Okay. I want to ask you</p> <p>4 about a couple of words in here from a</p> <p>5 common sense perspective. And you can</p> <p>6 just tell me whether you know this</p> <p>7 information or not.</p> <p>8 So that last sentence we</p> <p>9 were looking at in this document that</p> <p>10 says, "Qualitatively, the metabolism of</p> <p>11 NDMA appears to be similar in humans and</p> <p>12 animals. As a result it is considered</p> <p>13 highly likely that NDMA is carcinogenic,</p> <p>14 potentially at relatively low levels of</p> <p>15 exposure."</p> <p>16 Can we agree that low levels</p> <p>17 of exposure means not very much NDMA</p> <p>18 exposure?</p> <p>19 A. It is not quantified here.</p> <p>20 And say the low level, high level, minute</p> <p>21 level, cannot be justified on this. It</p> <p>22 is not being quantified.</p> <p>23 Q. Okay. What does the word</p> <p>24 "low" mean to you?</p>
<p>Page 39</p> <p>1 study, okay.</p> <p>2 MS. BRANCATO: Objection to</p> <p>3 form. The topic is Torrent's</p> <p>4 knowledge. He's already testified</p> <p>5 that he's never read that study</p> <p>6 before.</p> <p>7 Do you want to ask him about</p> <p>8 Torrent's knowledge of the health</p> <p>9 risks? He's ready to talk about</p> <p>10 that.</p> <p>11 MS. PENDLEY: Okay.</p> <p>12 BY MS. PENDLEY:</p> <p>13 Q. So Torrent has never</p> <p>14 reviewed the World Health Organization</p> <p>15 document on NDMA?</p> <p>16 Mr. Jaiswal?</p> <p>17 A. Yeah.</p> <p>18 Q. So are you saying that</p> <p>19 Torrent has never reviewed the World</p> <p>20 Health Organization document on NDMA?</p> <p>21 A. No.</p> <p>22 Q. Okay. I want to ask you one</p> <p>23 more time to clarify for the record. Has</p> <p>24 Torrent reviewed the World Health</p>	<p>Page 41</p> <p>1 A. That is not indicated. I</p> <p>2 cannot be able to comment on it, low</p> <p>3 means how much low, because I was not</p> <p>4 involved in the study, what kind of</p> <p>5 detection level they had, what kind of</p> <p>6 studies they had done. It's difficult to</p> <p>7 comment what the low means, what it</p> <p>8 communicates.</p> <p>9 Q. Okay. Let's look at the</p> <p>10 next page and see if this helps a little</p> <p>11 bit. On Page 5, paragraph on the</p> <p>12 left-hand side at the top, the last</p> <p>13 sentence says, "NDMA is a genotoxic</p> <p>14 carcinogen, and exposure should be</p> <p>15 reduced to the extent possible."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. So this says we should limit</p> <p>19 people's exposure to NDMA, right?</p> <p>20 MS. BRANCATO: Objection to</p> <p>21 form. Foundation. Outside the</p> <p>22 scope.</p> <p>23 THE WITNESS: This is --</p> <p>24 link is being given here but</p>

<p>Page 42</p> <p>1 definitely I'm not able to comment 2 that whether it is -- how much it 3 is, but I never be part of this 4 kind of study. That's why I'm not 5 able to comment on this topic. 6 BY MS. PENDLEY: 7 Q. Okay. You mentioned that 8 you don't know if this is right or wrong. 9 Do you think the World 10 Health Organization is wrong about their 11 assessment on NDMA? 12 MS. BRANCATO: Same 13 objections. 14 THE WITNESS: I'm not saying 15 that on the study, because I was 16 not involved in such kind of 17 studies, I'm not able to comment 18 on this topic. 19 BY MS. PENDLEY: 20 Q. Okay. You do know -- you 21 know, we looked at the date that this was 22 published before we went through the 23 actual text. It was published in 2002. 24 That is well before valsartan is</p> <p>Page 43</p> <p>1 recalled, correct? 2 MS. BRANCATO: Objection to 3 form. 4 BY MS. PENDLEY: 5 Q. You can answer. 6 A. Can I understand your 7 question once again? 8 Q. Yes. This document was 9 published in 2002. Do you remember 10 looking at that? 11 A. Yeah. 12 Q. 2002 is well before 2018 13 when the drug was recalled, right? 14 A. Yeah. 15 Q. Okay. So this information 16 was at least accessible by Torrent at the 17 time of the recall? 18 MS. BRANCATO: Objection to 19 form and foundation. 20 BY MS. PENDLEY: 21 Q. Right? 22 A. On this topic, maybe several 23 have in India, but this is not me, to the 24 best of my knowledge, we never accessed</p>	<p>Page 44</p> <p>1 this document. 2 Q. Well, if you look at the 3 very first page here, the page before the 4 cover page at the top, it says, "Document 5 produced in native format." 6 At the very bottom of that 7 page there's a little string of numbers 8 that start with TORRENT-MDL2875. 9 So what that means is we 10 actually got this document from Torrent. 11 So somebody at Torrent has seen this at 12 some point. 13 MS. BRANCATO: Is there a 14 question pending? 15 MS. PENDLEY: Yeah. 16 BY MS. PENDLEY: 17 Q. Correct? 18 MS. BRANCATO: Objection to 19 form and foundation. 20 BY MS. PENDLEY: 21 Q. You can still answer. 22 A. I'm not able to -- can I see 23 this document fully? 24 Q. If you want to. What I'm</p> <p>Page 45</p> <p>1 trying to direct your attention to is 2 just that it has what's called a Bates 3 stamp at the bottom. That just means 4 that we got it from you guys. 5 So somebody at Torrent had 6 this saved in their computer or sent in 7 an e-mail at some point. 8 Do you see that? 9 A. Can I -- can you share this 10 on the chat box so that I'm able to see 11 this document? 12 Q. The -- are you trying to 13 find the whole document again or just the 14 page that I'm talking about? 15 A. No, the page that you are 16 talking about. 17 Q. Okay. Yep, it should be the 18 document that you had pulled up from the 19 chat before. And it's just the very 20 first page. 21 A. That is 1102? 22 Q. Yes. 23 A. Okay. Torrent is written 24 here at the very bottom.</p>
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1 Q. Okay. So whether somebody
2 at Torrent reviewed this or not, this is
3 something that Torrent could have
4 reviewed at some point, right?
5 MS. BRANCATO: Object to
6 form and foundation.
7 Go ahead, Sushil.
8 THE WITNESS: Okay. You
9 see, the pharmaceutical people do
10 review big -- so many documents
11 and if somebody has seen this
12 document, is not in my knowledge.
13 BY MS. PENDLEY:
14 Q. Okay. What I'm trying to
15 get at is, when Torrent was told that
16 NDMA was in their drug, they could have
17 looked at documents like this to figure
18 out how dangerous NDMA was, right?
19 A. So whatever, like, post
20 discovery of the impurity, whatever work
21 is being required to be done required to
22 be report, everything is being done
23 appropriately.
24 Q. Okay. This information that

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1 was published in 2002 was accessible to
2 Torrent prior to the recall. We can
3 agree?
4 MS. BRANCATO: Objection to
5 form and foundation.
6 BY MS. PENDLEY:
7 Q. You can answer.
8 A. Not really. I'm -- still
9 I'm indicating that this is a very
10 general distribution likely is being
11 presented. But I've never seen this
12 document.
13 Q. Okay. I understand that you
14 haven't seen it. But it was published in
15 2002, right?
16 A. Yeah.
17 Q. And then the recall was in
18 2018, right?
19 A. Yeah.
20 Q. So this is something that
21 could have been reviewed by Torrent if
22 they wanted to review it; is that fair?
23 MS. BRANCATO: Same
24 objections.

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1 BY MS. PENDLEY:
2 Q. You can answer.
3 A. See, it's still -- my
4 argument is very limited to that aspect.
5 This studies might be done on some
6 understanding, but how much of this was
7 relevant I'm not aware of it. Whatever
8 it is scientifically needed to be in
9 investigation, that every scientific
10 database is being divulged at the time of
11 investigation.
12 Q. Okay. So am I correct in
13 understanding you said whatever
14 scientifically needed in an
15 investigations being divulged at the time
16 of the investigation. Is that what you
17 said?
18 A. Yeah.
19 Q. Okay. So whatever
20 information needs to be reviewed was
21 reviewed by Torrent?
22 A. Yes.
23 Q. But as the executive
24 director of quality at Torrent you had

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1 not seen this document before; that's
2 right?
3 A. Yeah.
4 Q. Okay. I want to ask you
5 about what one word means. We've seen
6 the word "genotoxic" a couple times
7 today. What does that word mean?
8 A. Can you repeat your
9 question?
10 Q. Yeah. What does genotoxic
11 mean?
12 A. I think I already indicated
13 that could be compounds which is being
14 identified that is inducing the
15 genotoxicity in the body.
16 Q. So you said a genotoxic
17 compound is what's inducing genotoxicity
18 in the body. What does that mean?
19 A. Yeah.
20 Q. What does genotoxicity in
21 the body mean?
22 A. That is basically -- that is
23 a kind of -- see, this is a certain kind
24 of -- this is a like -- a kind of

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1 compound that is inducing this maybe
2 genotoxicity in the body. This is what I
3 -- this is my understanding of this kind
4 of form.
5 Q. Okay. You're using the word
6 to define a word. So I'm having a hard
7 time understanding what it means. Can
8 you explain genotoxicity in some other
9 way?
10 A. Okay. So like ultimately
11 every compound has some threshold, for
12 this -- until -- unless that dose form is
13 not there in the body, it not impacting
14 you. Like that's what that
15 categorization molecule is one part. But
16 the threshold limit and beyond that, once
17 it is going, is impacting you in an
18 adverse way, is the second part.
19 This is the category of the
20 compound. And once it has gone beyond
21 that threshold level, this may cause you
22 a kind of impact to you. This is what is
23 my understanding of this category. And
24 these are carcinogenic.

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1 Q. So genotoxic is
2 carcinogenic. Is that what you're
3 saying?
4 A. Yes.
5 Q. Okay. Can we agree that
6 genotoxic compounds over a certain level
7 in pharmaceutical drugs should be taken
8 very seriously?
9 MS. BRANCATO: Objection to
10 form.
11 BY MS. PENDLEY:
12 Q. You can answer.
13 A. If you are -- I think this
14 is what I had answered, that for every
15 compound, there's a -- some threshold
16 limit. And not only the threshold limit,
17 beyond that the length of the treatment
18 and several other conditions are
19 associated with the patient.
20 And dose altogether,
21 combining together, only a physician can
22 say that -- what is the impact of that
23 threshold on the human body.
24 Q. Okay. Let me clarify this a

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1 little bit. So ideally, you would not
2 have genotoxic compounds in a drug. Is
3 that fair?
4 MS. BRANCATO: Objection to
5 form and foundation.
6 BY MS. PENDLEY:
7 Q. You can answer.
8 A. Yeah. Your question is
9 ideally supposed to be free from
10 genotoxic.
11 Q. Okay. So if you see there
12 is a genotoxic compound in a drug, that
13 should be investigated; is that fair?
14 A. You are correct.
15 Q. Because as you mentioned,
16 genotoxic compounds are dangerous above
17 threshold levels, so is it fair that the
18 company would need to find out whether or
19 not the genotoxic compound exceeds those
20 levels?
21 MS. BRANCATO: Objection to
22 form.
23 BY MS. PENDLEY:
24 Q. You can answer.

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1 A. No, I'm not able to
2 understood your question.
3 Q. Okay. You told me earlier
4 that genotoxic compounds are a problem if
5 they exceed a certain threshold level.
6 Do you remember that?
7 A. Yeah.
8 Q. Okay. So part of what you
9 would want to investigate is whether or
10 not that genotoxic compound exceeds those
11 threshold levels in the drug; is that
12 fair?
13 A. Like, in a drug, for a drug
14 substance, if genotoxic compound is not
15 identified, there is a guidance or level
16 to basically identify them and then to
17 devise a method. It was always there.
18 Q. Okay. So I'm going to
19 clarify a little bit. Would it be
20 important to investigate to make sure the
21 genotoxic compound is not over a certain
22 threshold level in a drug?
23 MS. BRANCATO: Objection to
24 form.

<p>Page 54</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MS. PENDLEY:</p> <p>3 Q. Okay. As you told me</p> <p>4 earlier, if a genotoxic compound is</p> <p>5 present and over the threshold limits,</p> <p>6 that's when it can cause health effects;</p> <p>7 is that right?</p> <p>8 MS. BRANCATO: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: That is what I</p> <p>11 indicated, but it depends upon so</p> <p>12 many other factors.</p> <p>13 BY MS. PENDLEY:</p> <p>14 Q. Right. Okay. But it's</p> <p>15 important to know whether or not</p> <p>16 genotoxic compounds are present at those</p> <p>17 threshold levels, right? Do you need me</p> <p>18 to repeat the question?</p> <p>19 A. Yeah.</p> <p>20 Q. Okay. It's important to</p> <p>21 know whether or not genotoxic compounds</p> <p>22 are present in a drug above the threshold</p> <p>23 levels, right?</p> <p>24 A. Yes.</p> <p>Page 55</p> <p>1 Q. Okay.</p> <p>2 MS. PENDLEY: Let's look at</p> <p>3 LP 1072.</p> <p>4 (Document marked for</p> <p>5 identification as Exhibit</p> <p>6 Torrent-217.)</p> <p>7 MS. PENDLEY: This is going</p> <p>8 to be marked Torrent Exhibit 217.</p> <p>9 Can we just look at the</p> <p>10 first page.</p> <p>11 BY MS. PENDLEY:</p> <p>12 Q. Mr. Jaiswal we see at the</p> <p>13 top of this document, it says the</p> <p>14 European Medicines Agency.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And a little further</p> <p>18 to the right it says June 2006. So this</p> <p>19 document was published in 2006.</p> <p>20 The title of it, do you see,</p> <p>21 "Guideline on the limits of genotoxic</p> <p>22 impurities"?</p> <p>23 A. Yeah.</p> <p>24 Q. All right. We're not going</p>	<p>Page 56</p> <p>1 to spend a lot of time on this. But I</p> <p>2 want to go to the fourth page in, I</p> <p>3 believe. They don't have page numbers:</p> <p>4 It starts with Number 4, "Toxicological</p> <p>5 background," at the top of the page.</p> <p>6 If we can look at that first</p> <p>7 paragraph. This says, "According to</p> <p>8 current regulatory practice, it is</p> <p>9 assumed that in vivo genotoxic compounds</p> <p>10 have the potential to damage DNA at any</p> <p>11 level of exposure and that such damage</p> <p>12 may lead or contribute to tumor</p> <p>13 development."</p> <p>14 Do you see that?</p> <p>15 A. Yeah.</p> <p>16 Q. Okay. So you told me</p> <p>17 earlier NDMA is a genotoxic compound,</p> <p>18 right?</p> <p>19 A. Yeah.</p> <p>20 Q. Okay. So we can read this</p> <p>21 in as NDMA has the potential to damage</p> <p>22 DNA at any level of exposure?</p> <p>23 MS. BRANCATO: Objection to</p> <p>24 form. Foundation. Outside the</p> <p>Page 57</p> <p>1 scope.</p> <p>2 BY MS. PENDLEY:</p> <p>3 Q. Do you see that?</p> <p>4 A. Yeah, I see that. Yeah.</p> <p>5 Q. Okay. Then it says, "Such</p> <p>6 damage may lead or contribute to tumor</p> <p>7 development."</p> <p>8 Do you see that?</p> <p>9 MS. BRANCATO: Objection.</p> <p>10 BY MS. PENDLEY:</p> <p>11 Q. Do you see that part,</p> <p>12 Mr. Jaiswal?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Then it goes on to</p> <p>15 say, "Thus, for genotoxic carcinogens, it</p> <p>16 is prudent to assume that there is no</p> <p>17 discernable threshold and that any level</p> <p>18 of exposure carries a risk."</p> <p>19 Do you see that?</p> <p>20 A. Yeah.</p> <p>21 Q. Okay. And like we said,</p> <p>22 NDMA is genotoxic, so we can read this in</p> <p>23 as for NDMA, it is prudent to assume</p> <p>24 there's no discernable threshold and that</p>
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<p>1 any level exposure carries a risk, right?</p> <p>2 MS. BRANCATO: Objection to</p> <p>3 form. Foundation. Outside the</p> <p>4 scope.</p> <p>5 BY MS. PENDLEY:</p> <p>6 Q. You can answer.</p> <p>7 A. This is a guidance which</p> <p>8 is -- must be based upon some studies,</p> <p>9 and may be each genotoxic compounds is to</p> <p>10 be behaving very differently. But this</p> <p>11 is a very general statement given here on</p> <p>12 the genotoxic compound. And what kind of</p> <p>13 format background distributed on these</p> <p>14 studies, on this guidance, I'm not able</p> <p>15 to offer.</p> <p>16 Q. Okay. But we can see that</p> <p>17 it says, "For genotoxic carcinogens, it's</p> <p>18 prudent to assume that there's no</p> <p>19 discernable threshold and any level of</p> <p>20 exposure carries a risk."</p> <p>21 Right?</p> <p>22 A. Yeah.</p> <p>23 Q. Okay. Now, had you ever</p> <p>24 seen this document before from the</p>	<p>1 Q. You can see at the top here,</p> <p>2 one in the upper right-hand corner,</p> <p>3 Torrent Pharma. This is a Torrent</p> <p>4 document, right?</p> <p>5 A. Getting downloaded.</p> <p>6 Q. Okay. Just let me know when</p> <p>7 you're ready. Okay.</p> <p>8 You got it?</p> <p>9 A. Yes.</p> <p>10 Q. Great. Upper right-hand</p> <p>11 corner, we see Torrent Pharma. So this</p> <p>12 is a Torrent document, right?</p> <p>13 A. Yes.</p> <p>14 Q. We see, "Health hazard</p> <p>15 evaluation." And underneath it says,</p> <p>16 "Amlodipine/valsartan/</p> <p>17 hydrochlorothiazide."</p> <p>18 This is a health hazard</p> <p>19 evaluation for valsartan, right?</p> <p>20 A. Yeah.</p> <p>21 Q. All right. Have you ever</p> <p>22 seen this document before?</p> <p>23 A. This is prepared by</p> <p>24 different team. That's why I'm not able</p>
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<p>1 European Medicines Agency?</p> <p>2 A. Yes, I've seen it.</p> <p>3 Q. You have, okay.</p> <p>4 Have you ever reviewed this</p> <p>5 document as it pertains to your job, to</p> <p>6 get more information or anything like</p> <p>7 that?</p> <p>8 A. I don't remember the access.</p> <p>9 But yes, I'm aware of this document.</p> <p>10 MS. PENDLEY: Okay. If we</p> <p>11 can look at LP 1065.</p> <p>12 MS. BRANCATO: Sushil, just</p> <p>13 remember to keep your voice up so</p> <p>14 that Michelle can hear you.</p> <p>15 THE WITNESS: Okay. Fine.</p> <p>16 (Document previously marked</p> <p>17 for identification as Exhibit</p> <p>18 Torrent-4.)</p> <p>19 MS. PENDLEY: For the record</p> <p>20 LP 1065 is previously marked as</p> <p>21 Torrent Exhibit 4.</p> <p>22 THE WITNESS: This is 1065?</p> <p>23 MS. PENDLEY: Yes.</p> <p>24 BY MS. PENDLEY:</p>	<p>1 to -- very sure whether I've seen this</p> <p>2 document.</p> <p>3 Q. Okay. Let's do something</p> <p>4 else real quick.</p> <p>5 MS. PENDLEY: Let's do LP</p> <p>6 1064.</p> <p>7 (Document previously marked</p> <p>8 for identification as Exhibit</p> <p>9 Torrent-3.)</p> <p>10 MS. PENDLEY: Previously</p> <p>11 marked as Torrent Exhibit 3.</p> <p>12 BY MS. PENDLEY:</p> <p>13 Q. All right. So this is an</p> <p>14 e-mail that this document was actually</p> <p>15 attached to. So we can see that it was</p> <p>16 sent August 18th, 2018, up at the top.</p> <p>17 A. Just a moment.</p> <p>18 Q. Okay.</p> <p>19 A. Yeah.</p> <p>20 Q. Okay. And then if you look</p> <p>21 down it's obviously sent to a bunch of</p> <p>22 people. But right -- it's close to the</p> <p>23 word subject on the left-hand side, we</p> <p>24 see your e-mail address there, right?</p>

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1 A. Yeah.
2 Q. Okay. So the attachment
3 that we see is, "HHE
4 valsartan/amlodipine/hydrochlorothiazide
5 medical assessment."
6 A. Yes, it is true.
7 Q. Okay. So the 1065 we looked
8 at was sent to you at some point, right?
9 A. Yeah.
10 Q. Okay. And that's okay. I
11 know it was a long time ago. But I
12 wanted to make that clear for the record.
13 So if we can pull up 1065 again. I want
14 to go to Page 3 of 5.
15 I want to look at the part
16 where it says, "Effect in animals."
17 That first little paragraph
18 says, "NDMA has been found to increase
19 the occurrence of cancer in animal
20 studies. Based on the animal studies
21 NDMA is considered a probable human
22 carcinogen, or a chemical that can
23 increase the risk of cancer in humans."
24 Do you see that?

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1 A. Yeah.
2 Q. Okay. So Torrent at the
3 time of the recall understood that NDMA
4 was a chemical that could increase the
5 risk of cancer in humans, right?
6 A. Yeah.
7 Q. Okay. We'll talk about this
8 more in a minute. But down at the bottom
9 of the page it says risk assessment. And
10 it says, "Consuming up to 96 nanograms of
11 NDMA per day is considered reasonably
12 safe for human ingestion."
13 That is the FDA limit,
14 right?
15 A. Yeah.
16 Q. Okay.
17 MS. PENDLEY: Can we take a
18 five-minute break. Is that good
19 with you?
20 THE WITNESS: That's fine.
21 THE VIDEOGRAPHER: The time
22 is now 7:03 a.m. (4:33 p.m. India
23 Time). We're going off the
24 record.

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1 (Short break.)
2 THE VIDEOGRAPHER: The time
3 is now 7:11 a.m. (4:41 p.m. India
4 Time). We're back on the record.
5 MS. PENDLEY: I want to look
6 at LP 1247.
7 (Document previously marked
8 for identification as Exhibit
9 Torrent-212-B.)
10 MS. PENDLEY: For the
11 record, this has already been
12 marked as Torrent Exhibit 212-B.
13 BY MS. PENDLEY:
14 Q. Okay. Do you see this first
15 page?
16 A. Yeah.
17 Q. All right. Again, we see
18 the Torrent Pharma logo at the top. We
19 see it's called "Valsartan Impact
20 Assessment of NDMA."
21 Do you see that?
22 A. Yes.
23 Q. Have you seen this document
24 before?

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1 A. I need to see the content,
2 and then I will tell you.
3 Q. Okay. You can flip through
4 it a little bit.
5 A. Just getting downloaded.
6 Yes, I've seen this.
7 Q. Okay. If we could go to the
8 third page. It's marked as Page 2 of 7.
9 This is going to give us a
10 little bit of background on why we're
11 here today. So we see at the top it
12 says, "Valsartan API is being used for
13 manufacturing of finished products. And
14 these finished products are being
15 supplied to U.S. market as per market
16 requirements."
17 Do you see that?
18 A. Yeah.
19 Q. And then it goes on to list
20 the different products that valsartan API
21 is used in. And it looks like there are
22 four.
23 A. Yes.
24 Q. Is that correct?

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1 A. Yes.

2 Q. Okay. At the bottom of this

3 page, we see, where it says note, and the

4 little asterisk. "Torrent has submitted

5 a withdrawal application to the FDA for

6 valsartan/hydrochlorothiazide in

7 November 2018," right?

8 A. Mm-hmm.

9 Q. Is that a yes?

10 A. Yes.

11 Q. Sorry, it's just for the

12 record.

13 So the three products that

14 we're left with at this point is solo

15 valsartan, valsartan/amlodipine and

16 valsartan/amlodipine/hydrochlorothiazide.

17 Right?

18 MS. BRANCATO: Object to the

19 form.

20 THE WITNESS: Yes.

21 BY MS. PENDLEY:

22 Q. Okay. We can go to the next

23 page, where it says, "Evaluation

24 methodology."

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1 It says, "Valsartan API is

2 being supplied by ZHP," and it gives the

3 DMF Number 23491.

4 Do you see that?

5 A. Yeah. Yes.

6 Q. Okay. Underneath in the

7 background of API process it says, "ZHP

8 used following two different API

9 manufacturing process for manufacturing

10 valsartan API."

11 Do you see where it says old

12 and new process?

13 A. Yes. C code and D code.

14 Q. Okay. Perfect.

15 Did you know that ZHP was

16 using two different processes?

17 MS. BRANCATO: Object to the

18 form.

19 THE WITNESS: Yes.

20 BY MS. PENDLEY:

21 Q. Okay. And it's my

22 understanding that Torrent, for the U.S.

23 product of valsartan, only ever used the

24 old manufacturing process; is that right?

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1 Or do you know?

2 Go ahead. I didn't hear

3 your answer.

4 A. Your question is that we

5 were using only the old process API?

6 Q. Yes.

7 A. That is correct.

8 Q. Okay. We see the old

9 process is C code batches, and we'll talk

10 about that in a second.

11 Further down it says, "ZHP

12 supplied old process C batches to

13 Torrent." Okay, great.

14 If we look at the next page.

15 This says, "Evaluation done by API

16 manufacturer" -- which would be ZHP,

17 right?

18 A. Yeah.

19 Q. It says, "Torrent

20 Pharmaceuticals Limited as a drug product

21 manufacturer asked ZHP for evaluation of

22 NDMA in their API lots."

23 So ZHP conducted their own

24 testing on their API product, right?

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1 A. Yeah, correct.

2 Q. Okay. At least for some

3 batches, we see here, but it looks like

4 there's eight separate batches, right?

5 A. Yeah, correct.

6 Q. So under results of NDMA, we

7 see that the first one is 63.4 parts per

8 million. And this is in the API,

9 correct?

10 A. This is in API.

11 Q. Not in the finished dose?

12 A. Not the finished dose, yeah,

13 correct.

14 Q. Okay. And you're aware that

15 the FDA limit for NDMA is .3 parts per

16 million, right?

17 A. When we were doing this

18 evaluation, that limit was not known.

19 Q. Okay. But now the limit is

20 .3 parts per million, right?

21 A. Yeah, that is correct.

22 Q. Okay. And so we see the

23 next row, 62.2, the next, 68.4. We can

24 see that these are all above 50 parts per

<p style="text-align: right;">Page 70</p> <p>1 million, right?</p> <p>2 A. Yeah, parts per million.</p> <p>3 Q. So all of these are close to</p> <p>4 200 times over the FDA limit for NDMA,</p> <p>5 right?</p> <p>6 MS. BRANCATO: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: That limit</p> <p>9 which is being given for -- and</p> <p>10 that is for the dosage form, not</p> <p>11 the API. And this is the</p> <p>12 compilation of the limit of the</p> <p>13 values for the API.</p> <p>14 BY MS. PENDLEY:</p> <p>15 Q. Okay. Well, does the FDA</p> <p>16 have a limit for API only?</p> <p>17 A. The FDA limit .3 is for the</p> <p>18 finished dose form.</p> <p>19 Q. Okay. So how much NDMA is</p> <p>20 allowed to be in the API?</p> <p>21 MS. BRANCATO: Objection to</p> <p>22 foundation.</p> <p>23 BY MS. PENDLEY:</p> <p>24 Q. You can answer.</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. Okay.</p> <p>2 A. -- that is above the limits.</p> <p>3 Q. All right. Let's look at</p> <p>4 the next page. This chart here at the</p> <p>5 top, it says, "Details of representative</p> <p>6 API lots analyzed are summarized below."</p> <p>7 So this chart says these are</p> <p>8 batches that went to the U.S., right?</p> <p>9 Under the market column, on the far left.</p> <p>10 Do you see that?</p> <p>11 A. Yeah, you're referring to</p> <p>12 the first column -- first?</p> <p>13 Q. Yeah.</p> <p>14 A. Yeah.</p> <p>15 Q. Okay. And then we see that</p> <p>16 it says a couple columns over, it says --</p> <p>17 the sixth column from the left. It says,</p> <p>18 "Number of FG batches manufactured using</p> <p>19 API lots."</p> <p>20 FG is finished goods; is</p> <p>21 that right?</p> <p>22 A. FG is finished goods, yeah.</p> <p>23 That's correct.</p> <p>24 Q. It says there's 119 finished</p>
<p style="text-align: right;">Page 71</p> <p>1 A. No, I'm not really aware of</p> <p>2 that, what it -- like, at that time, in</p> <p>3 fact, there was no limit there because at</p> <p>4 that time this was a discovery. And then</p> <p>5 -- neither for the API nor for the</p> <p>6 finished dose.</p> <p>7 Q. Okay. But based on what we</p> <p>8 know now, we know that the limit for</p> <p>9 finished dose is .3 parts per million,</p> <p>10 right?</p> <p>11 A. Yeah.</p> <p>12 Q. Okay. And we know that the</p> <p>13 API ultimately gets put into the finished</p> <p>14 dose product, right?</p> <p>15 A. Yeah. Correct.</p> <p>16 Q. So the API really shouldn't</p> <p>17 have more than .3 parts per million in it</p> <p>18 neither, right?</p> <p>19 A. Yeah, correct.</p> <p>20 Q. Okay. So each of these are</p> <p>21 over almost 200 times the FDA limit for</p> <p>22 the .3 parts per million, right?</p> <p>23 A. Yeah. These are above those</p> <p>24 limits which is -- we consider today --</p>	<p style="text-align: right;">Page 73</p> <p>1 dose batches using the API lots, right?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. And then the next</p> <p>4 column says, "Number of API lots tested,"</p> <p>5 29, right?</p> <p>6 A. Yeah. Correct.</p> <p>7 Q. And then the next column</p> <p>8 finished goods batches manufactured by</p> <p>9 tested API lots is 119. So is this</p> <p>10 saying that there are 29 API lots used in</p> <p>11 the 119 finished good batches?</p> <p>12 A. You are correct.</p> <p>13 Q. Okay. Great. Now I want to</p> <p>14 look at the chart below.</p> <p>15 So in this first row here</p> <p>16 again, if you can scroll through it a</p> <p>17 little bit. It looks like it lists all</p> <p>18 29 API batches for us, and then the</p> <p>19 testing levels for NDMA.</p> <p>20 Do you see that?</p> <p>21 A. Yeah.</p> <p>22 Q. Okay. So I just want to</p> <p>23 start with the first one and have you</p> <p>24 walk us through this.</p>

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1 So we can see this first row
2 it gives us the Torrent number for it and
3 then the C5069 is the ZHP batch number,
4 right?
5 A. Yeah, correct.
6 Q. Okay. And then the results
7 for NDMA in this batch in particular are
8 12.32 parts per million; is that right?
9 A. You're correct.
10 Q. Okay. I have a couple
11 questions about the way ZHP numbers their
12 batches. So you told me that the C5069
13 means it's old process, right?
14 A. Yeah, C is the old process.
15 Q. Okay. So any C batch is an
16 old process batch, right, no matter the
17 number?
18 A. Yes. C is the old process.
19 Q. Okay. And then it has 14
20 right here. So is 14 the year that this
21 batch was manufactured?
22 MS. BRANCATO: Objection.
23 Foundation.
24 THE WITNESS: I'm not sure,

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1 because this is a ZHP batch
2 numbering system. I'm not really
3 aware if that 14 stands for 2014
4 or something else.
5 BY MS. PENDLEY:
6 Q. Okay. So you don't know how
7 ZHP comes up with its batch number at
8 all?
9 A. Yeah.
10 Q. Okay. Do you know what the
11 shelf life is for ZHP's valsartan API?
12 A. I don't remember at this
13 point in time.
14 Q. Okay. What's the shelf life
15 for Torrent's finished dose valsartan?
16 Do you know?
17 A. That is something you can
18 check. I'm not remembering this, what is
19 the shelf -- because there are three
20 products involved. And my understanding,
21 I have to check the shelf life.
22 MS. BRANCATO: Sushil, just
23 keep your voice up, please.
24 THE WITNESS: Yeah.

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1 BY MS. PENDLEY:
2 Q. Okay. So you were a little
3 bit hard to hear. But did you say that
4 you don't remember the shelf life for
5 finished dose?
6 A. Because it's three products
7 and two combination. I really don't
8 remember the shelf life.
9 Q. Okay. That's fine. All
10 right. So what I'd like to do is I want
11 to compare this chart to a chart that's
12 in LP 1537.
13 MS. PENDLEY: So can we pull
14 1537 up as well and look at both.
15 (Document previously marked
16 for identification as Exhibit
17 Torrent 212-A.)
18 THE WITNESS: 15 -- can you
19 repeat?
20 MS. PENDLEY: Yeah, 1537.
21 I believe it's
22 Exhibit 212-A.
23 THE WITNESS: Yes, one
24 second. Impact assessment. NDEA.

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1 BY MS. PENDLEY:
2 Q. Okay. So basically, the
3 first couple pages of the new document,
4 1537, it's all the same summary as we
5 just looked at in the NDMA document. And
6 I'd like to go to Page 4 of 6 in 1537.
7 Okay. You see it's got that
8 other chart that we looked at saying
9 there's 119 batches, 29 API batches, and
10 so on. It's the same setup. Okay?
11 A. Correct.
12 Q. Okay. What is the FDA limit
13 for NDEA parts per million? Do you
14 remember that?
15 A. I suppose this NDEA be
16 evaluated post recalling all the batches
17 from the market.
18 Q. Yes, it is. And you know
19 that the FDA limit for NDEA for valsartan
20 is .083 parts per million, right?
21 A. Yeah, but I don't remember.
22 But yes, when we did this analysis at
23 that time, I think there was no maybe
24 limit by FDA, but we had our internal LOA

<p style="text-align: right;">Page 78</p> <p>1 level established.</p> <p>2 Q. Okay. But you know the</p> <p>3 limit now is .083 parts per million,</p> <p>4 right?</p> <p>5 A. For valsartan specific, I'm</p> <p>6 not sure. But yes, I understand the</p> <p>7 limit being is published by FDA. Because</p> <p>8 now valsartan is not the product with us.</p> <p>9 And that will -- and the new limit, I'm</p> <p>10 not really -- the numbering of it,</p> <p>11 weren't aware of it.</p> <p>12 Q. You said valsartan is not</p> <p>13 the product with us. What does that</p> <p>14 mean?</p> <p>15 A. We stopped manufacturing of</p> <p>16 this product since then. Since then</p> <p>17 we're not manufacturing this product</p> <p>18 anymore.</p> <p>19 Q. Okay. So we see that these</p> <p>20 documents both list the Torrent batch</p> <p>21 numbers and ZHP batch numbers. And they</p> <p>22 actually go in the same order. So they</p> <p>23 both start with the ARI11B0019.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 80</p> <p>1 working on the calculator, if we</p> <p>2 can pull up LP 1469.</p> <p>3 (Document previously marked</p> <p>4 for identification as Exhibit</p> <p>5 Torrent-77.)</p> <p>6 MS. PENDLEY: It'll be</p> <p>7 marked as Exhibit 218.</p> <p>8 THE WITNESS: 1537?</p> <p>9 MS. PENDLEY: 1469. This</p> <p>10 exhibit has actually been</p> <p>11 premarked as Torrent Exhibit 77.</p> <p>12 TRIAL TECH: Did you say</p> <p>13 calculator?</p> <p>14 MS. PENDLEY: Yes, please.</p> <p>15 If you have got a little</p> <p>16 calculator function on your</p> <p>17 computer.</p> <p>18 Can you pull up LP 1469 for</p> <p>19 us real quick, and then we'll come</p> <p>20 back to this.</p> <p>21 BY MS. PENDLEY:</p> <p>22 Q. Mr. Jaiswal, do you see this</p> <p>23 document?</p> <p>24 Mr. Jaiswal, do you see this</p>
<p style="text-align: right;">Page 79</p> <p>1 A. Yeah. This is internal rec</p> <p>2 number.</p> <p>3 Q. Okay. So looking at 1457.</p> <p>4 We can see that that batch, like you told</p> <p>5 me has 12.3 parts per million of NDMA,</p> <p>6 right?</p> <p>7 A. Mm-hmm.</p> <p>8 Q. Is that a yes?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And then we can see</p> <p>11 that that same batch, looking at 1537,</p> <p>12 has 7.89 parts per million for NDEA,</p> <p>13 right?</p> <p>14 A. Yeah.</p> <p>15 Q. And so what I'd like to do,</p> <p>16 if we could, for the trial tech is pull</p> <p>17 the calculator so we can see how this</p> <p>18 relates to the FDA limit.</p> <p>19 A. For valsartan is listed</p> <p>20 here, I'm not able to comment what the</p> <p>21 correct limit, because I don't remember</p> <p>22 that.</p> <p>23 Q. Okay. I'll show it to you.</p> <p>24 MS. PENDLEY: So while we're</p>	<p style="text-align: right;">Page 81</p> <p>1 document?</p> <p>2 A. Yes, I see this document.</p> <p>3 Q. Okay. Sorry.</p> <p>4 So we can see here it says,</p> <p>5 "Interim limits for NDMA, NDEA," and</p> <p>6 other nitrosamines.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And then it says</p> <p>10 valsartan on the left-hand side. Two</p> <p>11 columns over, "Acceptable intake for</p> <p>12 NDMA," nanograms per day is 96.</p> <p>13 Do you see that?</p> <p>14 A. Yeah.</p> <p>15 Q. The parts per million is .3,</p> <p>16 right?</p> <p>17 A. Yeah. It's true.</p> <p>18 Q. So the FDA limit for parts</p> <p>19 per million of NDMA for valsartan is</p> <p>20 .3 parts per million. You can agree?</p> <p>21 A. Yes. This is the FDA, I</p> <p>22 think, publication.</p> <p>23 Q. Okay. A couple columns over</p> <p>24 it says acceptable intake for NDEA in</p>

<p style="text-align: right;">Page 82</p> <p>1 parts per million is .083, right?</p> <p>2 A. Yeah.</p> <p>3 Q. Okay. So now that we</p> <p>4 understand the FDA limits, let's go back</p> <p>5 to 1537 and 1247.</p> <p>6 MS. PENDLEY: Is it possible</p> <p>7 to use the calculator?</p> <p>8 (Whereupon, a discussion was</p> <p>9 held off the stenographic record.)</p> <p>10 MS. PENDLEY: Okay, great.</p> <p>11 BY MS. PENDLEY:</p> <p>12 Q. So what I want to do is for</p> <p>13 1247, the NDMA levels, I want to divide</p> <p>14 12.32 by .3.</p> <p>15 TRIAL TECH: Say it one more</p> <p>16 time. Sorry.</p> <p>17 MS. PENDLEY: You could do</p> <p>18 12.32 divided by .3.</p> <p>19 BY MS. PENDLEY:</p> <p>20 Q. We can see that this batch</p> <p>21 has 41 times the FDA limit of NDMA in it,</p> <p>22 right?</p> <p>23 A. Yeah. That's correct.</p> <p>24 Q. Okay. And then looking at</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. Okay. So this is over 95</p> <p>2 times the FDA limit for NDEA, right?</p> <p>3 A. Yeah, that is correct.</p> <p>4 Q. Okay. So now we're going to</p> <p>5 look at the next batch. We're going to</p> <p>6 look at the Document 1247.</p> <p>7 MR. PENDLEY: And to the</p> <p>8 trial tech, if you can put in that</p> <p>9 number. 12.88.</p> <p>10 You've got the 12.88 divided</p> <p>11 by .03. .3, I mean. Sorry. I</p> <p>12 misspoke.</p> <p>13 THE WITNESS: .3, yeah.</p> <p>14 MS. PENDLEY: 12.88 divided</p> <p>15 by .3.</p> <p>16 BY MS. PENDLEY:</p> <p>17 Q. We can see the second batch</p> <p>18 has 42 times the FDA limit of NDMA,</p> <p>19 right?</p> <p>20 A. And we recalled all these</p> <p>21 batches.</p> <p>22 Q. Okay. Yes, you did, because</p> <p>23 they all contained more than the FDA</p> <p>24 limit of NDMA, right?</p>
<p style="text-align: right;">Page 83</p> <p>1 1537.</p> <p>2 MS. PENDLEY: To the trial</p> <p>3 tech, if I could have you put in</p> <p>4 7.89.</p> <p>5 7.89, please, divided by</p> <p>6 .083.</p> <p>7 BY MS. PENDLEY:</p> <p>8 Q. So we can see that the same</p> <p>9 batch has over 95 times the FDA limit of</p> <p>10 NDEA, right?</p> <p>11 A. So that is correct. But</p> <p>12 according to me, for NDEA and NDMA, for</p> <p>13 other impurities, now the current</p> <p>14 computation is .3; is that correct? Can</p> <p>15 I check back on this topic?</p> <p>16 Q. Are you asking if the</p> <p>17 impurity for NDEA and NDMA is .3?</p> <p>18 A. Yeah.</p> <p>19 Q. We just looked at the FDA</p> <p>20 limit for NDEA.</p> <p>21 Do you remember that?</p> <p>22 A. Yeah.</p> <p>23 Q. And it was .083.</p> <p>24 A. Okay. Fine.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Well, at that time, we were</p> <p>2 not knowing the limit. But we still,</p> <p>3 because it is being identified with these</p> <p>4 impurities, that's why.</p> <p>5 Q. Okay. We'll talk about that</p> <p>6 in just a second because I'm going to</p> <p>7 show you the date this document is from.</p> <p>8 But for the sake of the trial tech, we're</p> <p>9 going to move through a couple of these</p> <p>10 before I make him take all this down.</p> <p>11 So we've got 42 times the</p> <p>12 limit of NDMA in this second batch,</p> <p>13 right?</p> <p>14 A. Yeah.</p> <p>15 Q. Okay. And looking at 1537,</p> <p>16 that same batch for NDEA. 7.12 divided</p> <p>17 by .083.</p> <p>18 So about 85 times the FDA</p> <p>19 limit of NDEA, right?</p> <p>20 A. Mm-hmm. Yes.</p> <p>21 Q. Okay. In the same batch.</p> <p>22 Now we're going to skip down</p> <p>23 some. We're not going to do this for</p> <p>24 every row.</p>

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1 MS. PENDLEY: Let's look at
2 Row 15 on the 1247 document. And
3 it'll be on the next page of 1537.
4 BY MS. PENDLEY:
5 Q. Okay. So let's do 65.29
6 divided by .3.
7 So we can see that this
8 batch is 217 times the FDA limit for
9 NDMA, right?
10 A. Yeah.
11 Q. All right. Looking at Row
12 15 on 1537, let's do 6.02 divided by
13 .083.
14 So this batch also has over
15 72 times the FDA limit of NDEA, right?
16 A. Yeah. Correct.
17 Q. Okay. Let's do Row 20 on
18 1247.
19 MS. PENDLEY: So if you can
20 put in -- it's going to be on the
21 next page. If you can put in
22 125.03 divided by .3.
23 BY MS. PENDLEY:
24 Q. So this batch has 416 times

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1 the FDA limit of NDMA, right?
2 A. Yeah, correct.
3 Q. Okay. Then we see several
4 of these all the way down. The next one
5 has 116, 116, 111, 108.
6 Do you see all of those?
7 Do you see that column,
8 Mr. Jaiswal, the results of NDMA on 1247?
9 A. Yes.
10 Q. Okay. And so all of those
11 that are in the hundreds are roughly 300
12 times the FDA limit for NDMA, right?
13 MS. BRANCATO: Objection to
14 form.
15 BY MS. PENDLEY:
16 Q. Right?
17 Mr. Jaiswal, do you see what
18 I'm talking about?
19 A. Yeah. This like -- like, if
20 we can see the current limits.
21 Q. So my question is, we can
22 see all of those batches that have over
23 100 parts per million of NDMA, those are
24 all roughly over 300 times over the FDA

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1 limit, right?
2 MS. BRANCATO: Same
3 objection.
4 BY MS. PENDLEY:
5 Q. Right?
6 A. Yeah, it's correct against
7 the current limits.
8 Q. What do you mean by that?
9 A. Because these limits were
10 not known that moment of time. But if we
11 consider the current limits, which has
12 been published by FDA, yes, right.
13 Q. Okay. So what these
14 documents show us is that all of these
15 batches in 1247 have more than .3 parts
16 per million for NDMA, right?
17 A. In every batch, I think
18 there's a different level of
19 observations, and from which API, how
20 many batches are manufactured, there's a
21 difference upon that. And that's why
22 this data is here, which is -- we
23 identified.
24 Q. Okay. Let me ask the

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1 question again. So this document lists
2 all 29 API batches that were used, right?
3 A. Yes, correct.
4 Q. And every single one of them
5 contains more than .3 parts per million
6 of NDMA, right?
7 A. Yeah, correct.
8 Q. Okay. So every single one
9 of the API batches is over the FDA
10 threshold limit; is that fair?
11 A. Correct.
12 Q. Okay. And for NDEA, most of
13 these are over the .083 parts per
14 million, right?
15 A. Yes.
16 MS. BRANCATO: Object to the
17 form.
18 BY MS. PENDLEY:
19 Q. So then most of these are
20 over the threshold for NDEA as well?
21 MS. BRANCATO: Same
22 objection.
23 BY MS. PENDLEY:
24 Q. Right?

<p style="text-align: right;">Page 90</p> <p>1 Is that right?</p> <p>2 A. Yeah. Again, I'm indicating</p> <p>3 that, yes, if we consider the current</p> <p>4 limits, yes -- considering the current</p> <p>5 limit, yes, it is above the threshold</p> <p>6 limit.</p> <p>7 Q. Okay. You do realize that</p> <p>8 these threshold levels from the FDA were</p> <p>9 able to be calculated for NDMA and NDEA</p> <p>10 by following the ICH M7 guidelines,</p> <p>11 correct?</p> <p>12 MS. BRANCATO: Objection to</p> <p>13 form and foundation.</p> <p>14 BY MS. PENDLEY:</p> <p>15 Q. You can answer.</p> <p>16 A. I'm not really sure about</p> <p>17 it, because this is a different</p> <p>18 department who does this calculation.</p> <p>19 I'm not really sure.</p> <p>20 Q. Okay. But you were the head</p> <p>21 of quality at the time of this recall,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. So you were involved</p>	<p style="text-align: right;">Page 92</p> <p>1 recall, we have not tested for that NDEA.</p> <p>2 We were not knowing about the NDEA.</p> <p>3 Q. Okay. So focusing just on</p> <p>4 NDMA, did you recall as soon as you knew</p> <p>5 NDMA was present? Is that what you're</p> <p>6 saying?</p> <p>7 A. No.</p> <p>8 MS. BRANCATO: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: As soon as we</p> <p>11 identified and quantified the</p> <p>12 impurities, we recalled the</p> <p>13 batches.</p> <p>14 BY MS. PENDLEY:</p> <p>15 Q. Okay. Right. So once you</p> <p>16 knew that NDMA was over that threshold,</p> <p>17 you recalled the drug, right?</p> <p>18 MS. BRANCATO: Objection to</p> <p>19 form. Mischaracterizes testimony.</p> <p>20 BY MS. PENDLEY:</p> <p>21 Q. You can answer.</p> <p>22 A. Until -- unless we were not</p> <p>23 having quantifiable data, at that time we</p> <p>24 are not taking recall. As soon as we got</p>
<p style="text-align: right;">Page 91</p> <p>1 with the decision to recall this drug,</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. And so in order to decide</p> <p>5 whether or not to recall, you would need</p> <p>6 to know whether or not the NDMA exceeds</p> <p>7 the FDA threshold, right?</p> <p>8 MS. BRANCATO: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: That's</p> <p>11 correct.</p> <p>12 Our decision is not based</p> <p>13 upon that aspect. Our decision</p> <p>14 was based upon because the</p> <p>15 impurities being identified, which</p> <p>16 was not earlier known, and that's</p> <p>17 why we are taking the decision to</p> <p>18 recall all the batches.</p> <p>19 BY MS. PENDLEY:</p> <p>20 Q. So you're saying that you</p> <p>21 guys made the decision to recall solely</p> <p>22 based on the presence of NDMA; is that</p> <p>23 right?</p> <p>24 A. Yeah. Because when we</p>	<p style="text-align: right;">Page 93</p> <p>1 the quantifiable data, we initiated</p> <p>2 recall.</p> <p>3 Q. Okay. Do you understand</p> <p>4 where that FDA threshold limit came from</p> <p>5 or how it was calculated?</p> <p>6 A. Yes.</p> <p>7 Q. Okay.</p> <p>8 A. We became aware of it.</p> <p>9 Q. Okay. So you know that it</p> <p>10 was based on calculations found in ICH M7</p> <p>11 guidelines, right?</p> <p>12 A. How FDA calculated, I'm not</p> <p>13 sure. But yes, this is the guidance</p> <p>14 available and it is being used to</p> <p>15 calculate that.</p> <p>16 Q. Okay. And you know that the</p> <p>17 ICH M7 guidelines were published before</p> <p>18 any company recalled its valsartan,</p> <p>19 correct?</p> <p>20 A. Yeah, M7 guideline.</p> <p>21 Q. Okay. As far as you're</p> <p>22 aware, all the lots that were within the</p> <p>23 expiration date of Torrent's valsartan</p> <p>24 was ultimately recalled, right?</p>

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1 A. Yes.
2 Q. Okay. And Torrent started
3 selling valsartan in approximately 2015;
4 is that right?
5 A. Your question is what?
6 Since when we are selling this medicines?
7 Q. Yes. I'm asking when did
8 Torrent start selling valsartan in the
9 U.S.? Was that 2015?
10 A. I'm not sure, but maybe from
11 that time or maybe from before that time.
12 I'm not really --
13 Q. Okay. Okay. So at least
14 2015; is that fair?
15 A. Yeah.
16 Q. Okay. Torrent, like you
17 told me earlier, only ever used the old
18 process for API, right?
19 A. Yes.
20 Q. Never switched to new
21 process, right?
22 A. Yeah, we never used the new
23 process.
24 Q. Okay. No other major

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1 manufacturing was changed to the API
2 process, as far as you're aware, right?
3 A. No. Can you repeat your
4 question?
5 Q. Yeah. So aside from the
6 new/old process issue, no other
7 significant manufacturing process change
8 was made to valsartan API in the U.S.?
9 MS. BRANCATO: Objection.
10 Foundation.
11 THE WITNESS: See, I'm not
12 able to comment on this, because
13 this is a ZHP process, and they
14 have only notified for this
15 change.
16 BY MS. PENDLEY:
17 Q. Okay, great. They have only
18 notified for this change. You're not
19 aware of anything else?
20 A. No.
21 Q. Okay. That's what I'm
22 trying to get at. Perfect.
23 MS. PENDLEY: So if we could
24 look at LP 1078.

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1 (Document previously marked
2 for identification as Exhibit
3 Torrent-16.)
4 THE COURT REPORTER:
5 Previously marked, Madeline?
6 MS. PENDLEY: Yep, as
7 Torrent-16.
8 BY MS. PENDLEY:
9 Q. If we can go to the first
10 page.
11 Mr. Jaiswal, can you see
12 this on your end?
13 A. Yes, I see this. This is
14 EMEA --
15 MS. BRANCATO: Whatever is
16 on the screen is incorrect.
17 MS. PENDLEY: You are right.
18 It is not. We're going to look at
19 1078, and it's Bates Number
20 TORRENT-MDL2875-00523126.
21 Perfect.
22 BY MS. PENDLEY:
23 Q. Okay. So we can see that
24 this is an e-mail.

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1 A. Yes.
2 Q. And looking at the top here,
3 it doesn't look like it was sent to you.
4 We can see the date is August 27th, 2018.
5 Do you see that?
6 A. Yes.
7 Q. All right. I want to go to
8 the next page. So this says, "Please
9 find NDMA result found in below old
10 process batches from Huahai."
11 Okay. And then it goes on
12 to say, "Please find the batches test
13 results as well as a list of batches
14 supplied to Torrent with old process from
15 2015."
16 Do you see that?
17 A. Just a moment. Which
18 statement you are referring to?
19 Q. Just that sentence right
20 there above the first chart on the second
21 page of the document.
22 A. Yeah.
23 Q. Okay. So this first chart
24 that says "API stocks available" lists

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1 ZHP's batch numbers and then a ppm of
2 NDMA.
3 Do you see that?
4 A. Yeah, I see that.
5 Q. All right. And then the
6 second chart provides a list of lot
7 numbers from 2015.
8 Do you see that?
9 A. Yes, I see that.
10 Q. All right. So I want to
11 look at both of these charts. Looking at
12 the chart that's lot numbers from 2015,
13 six up from the bottom, we see the batch
14 that is C5069-15-049M.
15 Do you see that one?
16 A. Can you repeat the number,
17 ma'am?
18 Q. Yeah, it's -- basically they
19 all start the same way. It ends in 049M.
20 A. Yeah.
21 Q. Okay. And we see that
22 number again in the API stocks available
23 chart.
24 A. Okay.

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1 Q. Four down from the top. So
2 we can see that that batch has 56.5 parts
3 per million of NDMA in it, right?
4 A. It is identified, yeah.
5 Q. Okay. So that's a batch
6 from 2015 that has 56.5 parts per million
7 of NDMA in it?
8 A. Yeah.
9 Q. Okay. The next one under
10 that, we've got the one that ends in 050.
11 And we see it end in the API chart,
12 right?
13 A. Yeah. Correct.
14 Q. 56.2 parts per million of
15 NDMA, right?
16 A. Yeah.
17 Q. The next one is in both
18 charts ending in 051M at 56.4 parts per
19 million of NDMA.
20 A. Yeah. 56.4.
21 Q. Okay. The next one, same
22 batch. The next one in both charts
23 ending in 052 has 51 parts per million of
24 NDMA.

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1 A. Yeah, correct.
2 Q. And the next ends in 53,
3 same both charts. It has 63.1 parts per
4 million of NDMA.
5 A. Yeah, correct.
6 Q. Okay. And then the top
7 three, ending in 038, 039, 041, on the
8 next page of the chart, but we can see
9 they all have 63.4, 62.2 and 68.4 parts
10 per million of NDMA, right?
11 A. Okay.
12 Q. So once again, all of these
13 are higher than the .3 parts per million
14 FDA threshold, right?
15 A. Yeah.
16 Q. And these were all batches
17 manufactured or at least in Torrent's
18 possession in 2015, right?
19 MS. BRANCATO: Objection to
20 form.
21 THE WITNESS: Yeah.
22 BY MS. PENDLEY:
23 Q. Okay. So we can see the
24 contamination goes back to at least 2015;

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1 is that fair?
2 MS. BRANCATO: Same
3 objection.
4 THE WITNESS: These --
5 BY MS. PENDLEY:
6 Q. Go ahead. You can answer.
7 A. So these are the, like,
8 batch numbers and lot numbers given. And
9 these are the -- with the reference to
10 the old process. And, say, based upon
11 the finished product expiry, versus which
12 lots is being used, once this has been
13 identified, we started tracking for all
14 the batches which are within the shelf
15 life, which API lots is being used.
16 And we were -- we started
17 collecting the data so that the
18 appropriate action would be taken up.
19 So this is in that sense,
20 these batch data of -- details of
21 impurities is being requested.
22 Q. Okay. No, I understand
23 that. My question is a little bit more
24 simpler. It's just, yes, these batches

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1 are from 2015, correct?

2 A. Because the date of

3 manufacturing not in here, so that's why

4 I'm not able to really comment on which

5 date of manufacturing these batches were

6 produced. And that's why I say I'm not

7 able to really comment on that, whether

8 this is for 2015 or '16 or '17.

9 Q. Okay. My mistake. I

10 understand what you're saying. So we can

11 agree at least the API batch is from

12 2015?

13 MS. BRANCATO: Same

14 objection.

15 THE WITNESS: This is from

16 the 2015 onward. But there may be

17 batches that were being supplied

18 in 2016, '17, '18 also, because we

19 requested this information in

20 2018.

21 BY MS. PENDLEY:

22 Q. Okay. Got it. We're going

23 to talk about testing a little bit now.

24 We can agree Torrent did not

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1 know how to test for nitrosamines at the

2 time of the recall, right?

3 MS. BRANCATO: Objection to

4 form.

5 BY MS. PENDLEY:

6 Q. You can answer.

7 A. At the time of recall, we

8 were -- we have tested the API lots. And

9 that's why I say, yes, we were unknown at

10 this time.

11 Q. Okay.

12 MS. PENDLEY: Let's take a

13 look at LP 682, previously marked

14 as Torrent Exhibit 12.

15 (Document previously marked

16 for identification as Exhibit

17 Torrent-12.)

18 BY MS. PENDLEY:

19 Q. This is an e-mail. The

20 first e-mail is actually at the back, so

21 if we can start on Page 2.

22 A. This mail is not legible.

23 Just a moment. Let me -- it's in the

24 chat. Just a moment. I'm going to see.

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1 MS. PENDLEY: Okay. Can we

2 go off the record for a second.

3 THE VIDEOGRAPHER: The time

4 is now 7:56 a.m.

5 Do you still want to go off,

6 Counsel?

7 MS. PENDLEY: Did he come

8 back?

9 THE WITNESS: Yeah, yeah.

10 MS. BRANCATO: Yeah, the

11 problem is -- Sushil, the

12 documents should be in the chat

13 available for you to download.

14 THE WITNESS: Okay. Sure.

15 Sorry.

16 BY MS. PENDLEY:

17 Q. That's okay.

18 A. This is 682 now?

19 Q. Yes. Let me know when you

20 have it.

21 A. Yeah.

22 Q. We'll go to Page 2.

23 A. Yeah.

24 Q. Okay. We can see this

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1 starts with an e-mail from Dawn Chitty.

2 Do you know who that is?

3 A. Yeah, I know.

4 Q. Who is she?

5 A. Hello?

6 Q. Can you hear me?

7 A. Yeah.

8 Q. Okay. Who is Dawn Chitty?

9 A. Dawn, she was our U.S.

10 regulatory lead. And she was responsible

11 for taking care of U.S. regulatory as

12 well as she was also communicating with

13 FDA on behalf of Torrent.

14 Q. Okay. Did you communicate

15 with Dawn Chitty regularly?

16 A. Not regularly, but yeah,

17 whenever -- like what demands, but

18 otherwise my team members, they used to

19 be in contact with Dawn Chitty.

20 Q. Okay. So we can see she

21 sends this e-mail to you. You're one of

22 the e-mail addresses listed there.

23 A. Yeah.

24 Q. The date is August 11, 2018.

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1 Do you see that?
2 A. Yes.
3 Q. So this is after Torrent was
4 aware their drug contained NDMA, right?
5 A. This is 11th August.
6 Q. Yes, which is after Torrent
7 learned their drug was contaminated,
8 right?
9 MS. BRANCATO: Objection to
10 form.
11 BY MS. PENDLEY:
12 Q. You can answer.
13 A. No, I'm trying to correlate
14 the dates versus when the method was
15 already -- at this time, I don't remember
16 the dates, on which date our method was
17 ready.
18 Q. Okay. At this point, on
19 August 11, 2018, we see at the bottom of
20 this paragraph that Dawn Chitty sends to
21 you, "Also, have we been able to develop
22 or transfer a method to test for NDMA?"
23 Right?
24 A. Yeah.

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1 Q. So at least on August 11th,
2 Torrent did not yet know how to test for
3 NDMA?
4 MS. BRANCATO: Objection to
5 form.
6 BY MS. PENDLEY:
7 Q. Right?
8 MS. BRANCATO: Same
9 objection.
10 BY MS. PENDLEY:
11 Q. You can answer.
12 A. Yeah, just I'm trying to
13 read the mail actually.
14 Q. Okay.
15 A. This I need to confirm the
16 dates, because she is just putting a
17 question mark. She's asking this,
18 whether we have a method developed or not
19 by this time.
20 Q. Okay. I'll show you another
21 document with the dates in just a second.
22 We can see, though, that on August 11th,
23 Dawn Chitty is asking, "Do we have a test
24 for NDMA," right?

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1 A. She is asking whether the
2 method is developed or not, kind of
3 question mark.
4 Q. Right. Okay. And then we
5 can see the response to her right above
6 it.
7 In about the middle of this
8 it says, "The method development to test
9 for NDMA is under progress." Right?
10 A. Yeah.
11 Q. Okay. So under progress
12 means it's not finalized yet?
13 A. So I'm not sure whether
14 development is over and validation is
15 going on, because the analytical method,
16 development and validation, these are the
17 two aspects to be developed by this time,
18 whether we have developed a method and it
19 was under validation. So this I need to
20 really check.
21 Q. Okay. But either way, even
22 if it's still in the validation process,
23 it's not totally ready, right?
24 MS. BRANCATO: Objection to

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1 form.
2 THE WITNESS: I cannot -- I
3 don't check the date. I'm not
4 able to comment on this.
5 BY MS. PENDLEY:
6 Q. I'm not asking you about the
7 date. I'm asking you about "under
8 progress." So if it says the test is
9 under progress, it means it's not fully
10 developed, right?
11 MS. BRANCATO: Objection to
12 form.
13 THE WITNESS: That's why I
14 say, if it is being developed,
15 then in the sense development is
16 completed. Then we know the
17 know-how. And then it requires a
18 validation.
19 BY MS. PENDLEY:
20 Q. Okay. So even if it still
21 requires validation, it's under progress,
22 it has not been validated yet; is that
23 fair?
24 MS. BRANCATO: Same

1 objection.
2 BY MS. PENDLEY:
3 Q. You can answer.
4 A. This implies that, yes,
5 maybe development is over or validation
6 is ongoing. And the method transfer is
7 only possible once you complete the
8 validation.
9 Q. You said the method transfer
10 is only possible once you complete the
11 validation; is that right?
12 A. Yeah.
13 MS. PENDLEY: Okay. Let's
14 look at LP 1039 previously marked
15 Torrent 13.
16 (Document previously marked
17 for identification as Exhibit
18 Torrent-13.)
19 BY MS. PENDLEY:
20 Q. Let me know when you have
21 it.
22 A. 1039?
23 Q. Yep.

<p>Page 114</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

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[REDACTED]

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1 MS. PENDLEY: Let's look at
2 LP 45 really quick.
3 (Document marked for
4 identification as Exhibit
5 Torrent-218.)
6 MS. PENDLEY: It will be
7 marked Exhibit 218. This is
8 TORRENT-MDL2875-00516411.
9 MS. BRANCATO: Sushil, do
10 you see it in the chat?
11 THE WITNESS: Yes, one
12 moment. I'm just downloading it.
13 BY MS. PENDLEY:
14 Q. If you want to go to page
15 34, we'll look at this in more detail in
16 just a second. Just to pull that date
17 for you?
18 A. Just a moment. It's being
19 downloaded.
20 Q. Okay. Let me know when
21 you're ready.
22 A. Yeah.
23 Q. All right. Page 3.
24 A. Page 3.

[REDACTED]

22 indicating that C batch was contaminated.
23 Q. Okay. I can show you. One
24 second.

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1 Q. Yes, sir.
2 A. Yeah, Page 3.
3 Q. Okay. And so about midway
4 through the page, it's that fourth little
5 sentence up from the bottom -- third
6 little sentence up from the bottom.
7 A. Mm-hmm.
8 Q. It says, "Further, the API
9 manufacturer communicated on August 3rd
10 that some batches of old process contain
11 this impurity."
12 Do you see that?
13 A. Just a moment. That is on
14 which date? Yes, that's correct.
15 Q. All right. So the e-mail
16 that we just looked at was from
17 August 18th, right?
18 A. This is for 28th August.
19 Q. Yes. This e-mail is from
20 August 28th. The one that we were just
21 looking at from your boss was from
22 August 11th, right -- August 18th?
23 A. Yeah. By 28th of August, we
24 were aware of it, that C lots are

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1 contaminated. But when that written --
2 what earlier mail that you're referring
3 to, on that day it was not.
4 Q. Well, no, so this e-mail
5 that actually you typed, if you want to
6 look at Page 1, bottom of the page, we
7 see it's from you, right?
8 A. Yeah.
9 Q. Okay. So you're listing out
10 a timeline of what y'all had been doing
11 with ZHP, right?
12 A. Just a moment.
13 Yes, this mail is of 28th of
14 August.
15 Q. Right. In your e-mail you
16 say the API manufacturer communicated on
17 August 3rd that some batches of old
18 process contained the impurity.
19 Do you see that?
20 A. Just a moment.
21 Q. It's on Page 3.
22 A. Yeah. It is correct.
23 Q. Okay. So that means on
24 August 3rd, Torrent was aware their C

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1 batches contained the impurity, right?
2 A. Yes. Torrent was aware.
3 But I was not aware of it.
4 Q. Okay. That's fine. Torrent
5 was aware on August 3rd, we can agree?
6 A. Agreed.
7 Q. Okay. But you're saying you
8 as head of quality were not informed of
9 this?
10 A. Yeah, because on 3rd of
11 August, the mail has come to our
12 procurement department.
13 MS. BRANCATO: I'm sorry.
14 Madeline, we're just going to have
15 to pause here.
16 Mahesh Agrawal is a lawyer
17 at Torrent. And so I believe this
18 e-mail should be privileged. And
19 so we're going to claw this back.
20 We'll send you a letter and priv
21 log for it.
22 If we can take it off the
23 screen, Jeff. That would be
24 great. Thank you.

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1 MS. PENDLEY: One second.
2 Let's go off the record for a
3 second.
4 THE VIDEOGRAPHER: The time
5 now is 8:16 a.m. We're going off
6 the record.
7 (Short break.)
8 THE VIDEOGRAPHER: The time
9 is now 8:21 a.m. We're back on
10 the record.
11 MR. NIGH: This is Daniel
12 Nigh, for the record, representing
13 plaintiffs.
14 Before we took a brief break
15 for technical issues, there was a
16 request to claw back this document
17 that's been marked as Torrent
18 Exhibit 218.
19 I wanted to note for the
20 record this has been used
21 previously in several depositions.
22 This is the first time that
23 there's been a clawback request.
24 My first question to Lexi

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1 is, who is the lawyer that you're
2 referring to that would make this
3 document privileged?
4 MS. BRANCATO: Mahesh
5 Agrawal is an attorney at Torrent.
6 What was the previous exhibit
7 number? 218.
8 MR. NIGH: Exhibit 218.
9 MS. BRANCATO: I see. So
10 it's just 218. There are no other
11 exhibit numbers.
12 MR. NIGH: I can't represent
13 there are other exhibit numbers.
14 But I know it's Exhibit 218.
15 MS. BRANCATO: Got it.
16 Okay. Well, I think we can
17 address this via letter or via
18 e-mail later.
19 MR. NIGH: Well, I think we
20 need to address it now because we
21 intend to use it now. So I'm
22 trying to see -- again, I didn't
23 hear the name.
24 Who was the lawyer that you

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1 said, the Torrent lawyer.
2 MS. BRANCATO: Mahesh
3 Agrawal. What depositions was
4 this used at previously?
5 MR. NIGH: Do you guys know?
6 MS. PENDLEY: Dawn Chitty
7 and Rivera.
8 MR. NIGH: At least. At the
9 point our argument will be, as we
10 look at the text of this
11 information, it troubles plaintiff
12 counsel to suggest that this
13 communication would be
14 communication that is the type of
15 communication that would be
16 privileged communication.
17 We would also suggest that
18 by looking at this communication,
19 we would wonder whether or not
20 attorneys have marked other
21 documents privileged, similarly to
22 this document, seeing as how we
23 look at the text of the
24 information, we do not believe

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1 that this is confidential
2 information or information that
3 would rise to that standard.
4 Additionally, we believe
5 that this has been used at
6 multiple depositions. This
7 confidentiality has been waived at
8 this time.
9 Also, we believe that it is
10 untimely, that in the middle of a
11 deposition while we're questioning
12 on the document, that there is a
13 request to clawback the document.
14 We believe that we should be
15 able to go forward on this
16 document at this time, and we'll
17 await defense argument.
18 MS. BRANCATO: I'm not
19 planning on responding to every
20 point that was raised in that
21 argument.
22 Our position is that the
23 document is privileged, and my
24 suggestion is that we move on from

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1 this document for now, and while
2 you continue to question the
3 witness, we can look into where
4 this document was used previously,
5 the exhibit numbers, whether in
6 fact it was used previously, and
7 then we can talk about it on our
8 next break or later today or
9 during the two remaining days of
10 deposition.
11 MR. NIGH: I would disagree
12 with that. And I would still say
13 that that frustrates and
14 prejudices our attempt to lay
15 foundations we prepared for this
16 deposition.
17 Trying to go out of order,
18 this is simply -- this has a lot
19 of foundational questions that
20 give us the timeline of events
21 that are going to set up the rest
22 of the deposition.
23 So counsel's suggestion that
24 we come back to it really would

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1 put things out of order. And
2 we've waited this time. And we
3 should be able to proceed forward.
4 If counsel instructs the
5 witness not to answer questions
6 regarding this document, we will
7 be seeking sanctions in regards to
8 the prejudice that we had in
9 disrupting the deposition of this
10 important 30(b)(6) witness.
11 MS. BRANCATO: Obviously, we
12 disagree that there's any
13 prejudice to pausing on this one
14 document and coming back to it
15 later in the remaining two days of
16 testimony, and that there are
17 additionally thousands of other
18 documents that you can use to
19 establish the timeline.
20 Regardless, to avoid the
21 dispute and to avoid wasting your
22 time on the record, we can go off
23 the record now and we can assess
24 the privilege now, if that's the

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1 issue.

2 MR. NIGH: We'd like to

3 continue to go on the record since

4 there is a request for a clawback

5 made on the record.

6 In addition, whether or not

7 there are other documents that

8 could be pieced together to make a

9 timeline, we have prepped for this

10 deposition, we are using a

11 document that has been used in

12 multiple other depositions, it has

13 clearly prejudiced our attempt to

14 be able to lay out the foundation

15 of questions as we desired to lay

16 them out.

17 So we don't have time to go

18 back to try to set up other

19 documents that are going to lay

20 the foundation in terms of key

21 dates.

22 This is the document that we

23 choose to use. It's been used in

24 multiple other depositions. And

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1 in the middle of -- in the middle

2 of the deposition, there has been

3 an interruption, a request to claw

4 back a document that has been used

5 multiple times.

6 And it does prejudice our

7 attempt to in the order in which

8 we seek to lay a foundation for

9 this deposition.

10 MS. BRANCATO: I'm trying to

11 cut through this and stop wasting

12 your time so that you can use your

13 deposition time effectively. If

14 you allow us to go off the record

15 and give us 15 minutes to

16 investigate whether or not we want

17 to claw this document back and

18 your representation that it's been

19 previously used, we can move

20 through this quickly. And I can

21 give you an answer in 15 minutes.

22 MR. NIGH: Okay. Let's do

23 this. Let go ahead and take a

24 break. We'll take a 15-minute

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1 break and we'll come back and

2 restart the deposition.

3 THE VIDEOGRAPHER: The time

4 is now 8:26 a.m. We're going off

5 the record.

6 (Short break.)

7 THE VIDEOGRAPHER: The time

8 is now 8:49 a.m. (6:09 p.m. India

9 Time). We are back on the record.

10 MR. NIGH: This is Daniel

11 Nigh for the plaintiffs. I wanted

12 to retract one statement that I

13 said, that this document has been

14 used in previous depositions.

15 We're not sure that it has

16 been. So I'm going to retract

17 that part of the argument.

18 However, as looking at the

19 document, we believe that there's

20 none of this information that is

21 confidential in nature which would

22 be the most important thing in

23 determining whether or not it's a

24 privileged document.

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1 It certainly has us question

2 other privilege designations if

3 that's the determination that has

4 been made by defense lawyer as

5 said previously, because there is

6 a lawyer on the document, that it

7 would be privileged.

8 Even in looking at the

9 document, frankly argues -- it is

10 that -- it suits -- it is the

11 witness's recollection of dates

12 where he lays out a chronology of

13 events.

14 And here today, he has

15 mentioned multiple times that he

16 doesn't remember. Even though

17 he's been designated as a 30(b)(6)

18 witness, he doesn't remember

19 several of these dates.

20 So we're attempting to use

21 this e-mail from his own writing

22 to refresh his recollection of

23 these dates.

24 Frankly, we believe there's

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1 nothing confidential in terms of
2 the chronology of events that he's
3 given.
4 In addition, I would also
5 relate that the very first part of
6 the e-mail chain that is from
7 Mahesh Agrawal, the defense
8 lawyers are stating is the lawyer
9 that would make this information
10 privileged, the document states,
11 even there, from him, it says,
12 "This refers to our telecon
13 August 18th. We await the note on
14 the matter for taking it up with
15 the lawyer."
16 And so obviously there's
17 another lawyer involved that they
18 are looking to pass information on
19 to.
20 But he even refers this to
21 "with the lawyer." So again, I
22 believe that even this claimed
23 lawyer is not even referring to
24 himself as a lawyer.

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1 I would also mention that,
2 again, the information is not
3 confidential in nature. But I'd
4 also mention that the title of
5 this person, the Mahesh Agrawal,
6 just looking at the title, VP of
7 legal compliance and company
8 secretary, so frankly is more of a
9 business lawyer, wears the hat,
10 but still conducting business, an
11 and I believe that would be a
12 clear exception to the lawyer
13 privilege information.
14 So there's multiple reasons
15 as to why this document would not
16 be privileged.
17 And in addition, we believe
18 that the clawback procedure has
19 not been appropriately followed.
20 At this point, it cannot
21 just be defendants say we're
22 clawing back, you take down a
23 document. There's a procedure to
24 follow. We intend to proceed

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1 forward.
2 If defendants want to
3 instruct the witness not to
4 answer, they can do so on their
5 own dime. But we will certify the
6 question thereafter.
7 MS. BRANCATO: Okay. That
8 was quite a bit.
9 So first of all, Mahesh is
10 the lawyer at Torrent. The fact
11 that he may do business law does
12 not mean that he doesn't provide
13 legal advice and get asked for
14 legal advice at Torrent. That's
15 still all privileged.
16 So we object to any
17 representation that Mahesh's
18 documents may not be privileged
19 because he happens to also be
20 involved in the business or do
21 business law.
22 Regardless, for this
23 particular document we will
24 withdraw the clawback request and

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1 allow questioning on it.
2 MR. NIGH: Thank you.
3 BY MS. PENDLEY:
4 Q. Okay. So Mr. Jaiswal,
5 before this break, we were looking at LP
6 45. We're going to pick up there. Okay.
7 A. Yeah. Sure.
8 Q. And on Page 3. So you
9 remember this is an e-mail that you typed
10 out, right?
11 A. Yeah. Which -- Torrent 2,
12 3, which number do I need to open?
13 Q. LP 45. It's Torrent-218.
14 A. Torrent-218.
15 Q. Yep.
16 A. Yeah.
17 Q. All right. So looking at
18 the third page, back where we were
19 earlier, midway through the page where it
20 says, "Further, API manufacturer
21 communicated on 3rd August" -- do you see
22 that?
23 A. Yes.
24 Q. So you say, "The API

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1 manufacturer communicated on August 3rd
2 that some batches of old process also
3 contains this impurity, right?

4 A. Yes.

5 Q. So August 3rd is when ZHP
6 notified Torrent that NDMA was in
7 valsartan old process, right?

8 A. Yeah. That's correct.

9 Q. Okay. So we're going to go
10 back to LP 1039, Torrent-13.

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 Q. Okay, great. So I want to
11 shift gears just a little bit.
12 So you are aware that when
13 Torrent first developed valsartan, they
14 wanted to find a cheap API supplier,
15 right?
16 MS. BRANCATO: Objection to
17 form and foundation and outside
18 the scope of the 30(b)(6).
19 You can answer in your
20 personal capacity, if you know.
21 BY MS. PENDLEY:
22 Q. You can answer.
23 A. Now, which mail are you
24 referring?

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1 Q. I'll show you something.
2 MS. PENDLEY: Let look at LP
3 1047.
4 (Document previously marked
5 for identification as Exhibit
6 Torrent-7.)
7 BY MS. PENDLEY:
8 Q. Mr. Jaiswal, you mentioned
9 to me that you started at Torrent in
10 2017, right?
11 A. Yes.
12 Q. Okay. This e-mail, do you
13 have it pulled up yet?
14 A. This is in the exhibits?
15 THE VIDEOGRAPHER: The same
16 link that I just sent to you, it
17 should be in there if you refresh.
18 THE WITNESS: 218.
19 BY MS. PENDLEY:
20 Q. It should be Torrent-7.
21 A. Torrent-7.
22 Q. Yeah.
23 A. Sorry.
24 Q. You're fine.

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1 A. Just a moment.
2 Torrent-7.
3 Q. Okay. You got it?
4 Okay. So we can see that
5 this e-mail is from 2006.
6 Do you see that at the top?
7 A. Yeah. 2006, May.
8 Q. Okay. And this is way
9 before you started working there, right?
10 A. Yeah.
11 Q. All right. We can see that
12 this is sent to people with a
13 TorrentPharma.com e-mail address?
14 A. Mm-hmm.
15 Q. Is that a yes?
16 A. Yes.
17 Q. Okay. And so those would be
18 people that work at Torrent Pharma
19 Limited in India, right?
20 A. Yes.
21 Q. Okay. So in this e-mail, if
22 we scoot down a little bit, we can see
23 the e-mail says, "API processing."
24 And then in this chart it

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1 says valsartan, and across from that, it
2 says, "Develop a second source with
3 60 percent price reduction."
4 Right?
5 A. Yeah.
6 Q. I know you're not a sales
7 guy. But this says that they want to
8 develop a second source of API that's
9 60 percent cheaper, right?
10 MS. BRANCATO: Objection to
11 foundation. Form. And outside
12 the scope of the 30(b)(6).
13 THE WITNESS: Like costing,
14 I'm not able to comment about that
15 because pricing and costing is
16 all -- depends on what volume --
17 they buy what volume they
18 manufacture.
19 BY MS. PENDLEY:
20 Q. Okay. I understand that.
21 We can see the word "reduction" there,
22 right?
23 A. Yeah.
24 Q. And reduction means, you

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1 know, less; is that fair?
2 A. Yeah. Reduction means less.
3 Q. Okay. So this just says
4 develop a second source, you know, that's
5 60 percent less expensive; is that fair?
6 MS. BRANCATO: Same
7 objections.
8 THE WITNESS: Yeah. Written
9 in that mail.
10 BY MS. PENDLEY:
11 Q. Okay. This 2006. That's
12 years before Torrent's valsartan went on
13 the market, right?
14 A. This is year 2006. Maybe by
15 that time we have not been in the market.
16 MS. PENDLEY: Okay. Let's
17 look at LP 1088.
18 (Document marked for
19 identification as Exhibit
20 Torrent-8.)
21 MS. PENDLEY: I think this
22 is previously marked as Torrent-8.
23 THE WITNESS: Torrent-8?
24 MS. PENDLEY: Yes, sir.

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1 BY MS. PENDLEY:
[REDACTED]

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1 [REDACTED]

[REDACTED]

<p>Page 150</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

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21 Q. All right. Now, you are
22 familiar with gas chromatography, right?
23 A. Yes.
24 Q. Okay. This is going to be

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1 probably really, really simple. So just
2 bear with me.
3 A chromatogram shows little
4 peaks, right, for different ingredients?
5 A. So it depends upon, say you
6 are talking about gas chromatography?
7 Q. Yes.
8 A. In gas chromatography, yes,
9 definitely you're getting different peaks
10 and -- for the different compounds, it's
11 going to form a kind of format that you
12 have selected, a kind of map, the columns
13 you have in the process, and which kind
14 of substance you are analyzing.
15 Q. Okay.
16 A. It is -- like every -- every
17 compound is going to give a peak into the
18 chromatograms.
19 Q. Okay.
20 A. Yeah. So it's --
21 Q. So in order to figure out
22 everything that -- every compound that's
23 in a drug, for example, each compound
24 would have a little peak. Is that what

Page 158

1 you're saying? If it showed up --
2 A. No.
3 Q. -- on the test?
4 A. No. If you allow me to
5 elaborate a little bit.
6 To assess -- you have a
7 compound. And if you have ten different
8 components, like all ten components is
9 not going to be eluted be on the same
10 chromatogram. Depends the method of
11 analysis, the choice of column, and
12 different conditions and programs which
13 you feed in the gas chromatogram.
14 Q. Okay.
15 A. It's not going to --
16 immediately going give a kind of peak
17 into the chromatogram.
18 Q. Okay. So you have to adjust
19 the test you're conducting, you know,
20 depending on what you're looking for?
21 A. It is not a test method. It
22 is a development. Like you have this
23 target development for which kind of
24 analysis you are developing the method,

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1 and what is your target profile.
2 And based upon that
3 chromatographic method is being
4 developed, and then it is being
5 validated.
6 Q. Okay. So let's say you are
7 conducting residual solvent testing,
8 you're trying to see what kind of
9 solvents are present?
10 A. So it is not like that.
11 Because solvents are maybe for 100 --
12 more than 100 or more of that kind.
13 But you, to be able to do in
14 that fashion, the method is being
15 developed knowing a process,
16 understanding, like say the DMF -- API
17 manufacturer is using, say, suppose,
18 Solvent A in Stage 1, Solvent B in Stage
19 2 and Solvent C in Stage 3.
20 Based upon that knowledge,
21 basically they develop a method to
22 understand what is the A, B, and C
23 residual portion in the final API.
24 The method is designed by

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1 the DMF holder, in that sense, so you are
2 able to read A, B, and C in your drug
3 substance.
4 Q. Okay. So what happens if
5 you're testing your drug and you notice
6 there's a little peak that you guys
7 didn't think would be there?
8 MS. BRANCATO: Objection to
9 form.
10 BY MS. PENDLEY:
11 Q. Would you investigate it?
12 MS. BRANCATO: Same
13 objection.
14 BY MS. PENDLEY:
15 Q. You can answer.
16 A. Okay. So like, say -- for,
17 say, for the chromatography, there is a
18 set rule of the Pharmacopeia. And
19 Pharmacopeia defines that create a kind
20 of regulatory practices and limits for
21 that. And everything is being governed
22 by that.
23 If you have, like, a
24 secondary peak, then if it is -- there's

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1 some threshold. It has to be integrated.
2 It has to be reported. And if it is
3 within that some specification, then it
4 is fine. If it is not, then it has to be
5 detected. It has to be investigated.
6 Q. Okay. And then once you see
7 all those peaks, you guys typically label
8 each one, saying what they are; is that
9 right?
10 A. Yeah. If those are out of
11 specification, then basically -- you
12 basically discuss with your DMF holder
13 and then it become an exercise where
14 you're investigating these aspects.
15 MS. PENDLEY: Okay. So I
16 want to look at LP 1393 with you,
17 which has been previously marked
18 as Torrent-81.
19 (Document previously marked
20 for identification as Exhibit
21 Torrent-81)
22 THE WITNESS: Just a moment.
23 Which one?
24 MS. PENDLEY: Torrent-81.

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1 BY MS. PENDLEY:
2 Q. Just let me know when you
3 have it?
4 A. Just a moment. It's getting
5 downloaded.
6 Yeah, I'm able to see that.
7 Q. Okay. So in the upper
8 left-hand corner we can see this is from
9 December 30th, 2010. So, again, long
10 before you started at Torrent, right?
11 A. Yeah, this is a 2010
12 deficiency letter.
13 Q. Okay. Have you ever seen
14 this before?
15 A. No. Because this is for
16 2010, and this might be at the time of
17 assessment of -- I have not seen it.
18 Q. Okay. Got it. So we can
19 see that this is from the FDA to Torrent
20 Pharmaceuticals, specifically to Dawn
21 Chitty, right?
22 A. Yeah.
23 Q. All right. And in the
24 middle of the page, it says, "The

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1 Division of Chemistry has completed its
2 review and identified deficiencies."
3 Right?
4 A. Is it on the first page?
5 Q. Yes.
6 A. Yeah.
7 Q. Okay. So let's go to the
8 next page and see what the deficiencies
9 are. We can see under A, it says
10 deficiencies, and number one it says,
11 "Drug Master File 23491 was reviewed and
12 found to be deficient."
13 Do you see that?
14 A. Yeah.
15 Q. So that Drug Master File
16 23491, that's ZHP's DMF that you told me
17 about earlier, right?
18 MS. BRANCATO: Objection to
19 foundation.
20 THE WITNESS: Yeah.
21 BY MS. PENDLEY:
22 Q. Okay. If you look at Number
23 8 this list, it goes on to say, "In
24 validation report for dissolution

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1 testing, the list of chromatograms show
2 mostly the main peak, amlodipine;
3 however, in some chromatograms there are
4 unmarked peaks."
5 Do you see that?
6 A. Yeah, I see that.
7 Q. You told me earlier when you
8 guys are doing testing, you label every
9 peak, right?
10 MS. BRANCATO: Objection to
11 form.
12 THE WITNESS: For gas
13 chromatography, and this is -- we
14 are talking about the dissolution
15 testing.
16 BY MS. PENDLEY:
17 Q. Okay. So this is a
18 different kind of test?
19 A. Yeah, yeah, it is absolutely
20 different kind of test.
21 Q. Is it still important to
22 label peaks in any kind of test, or is
23 that just gas chromatography?
24 A. No. Once you are doing an

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1 impurity testing or that kind of testing,
2 then you do that kind of assessment.
3 This is principally going by
4 the chromatography practices, which is
5 well defined activity within the
6 chromatography -- within the USP and
7 within the guidance.
8 So then for the -- for the
9 dissolution test, this is fine, but for
10 the impurity testing, we need to identify
11 the impurities that could be going beyond
12 some threshold.
13 Q. Okay, great. This is very
14 helpful. Thank you.
15 Did anybody at Torrent, as
16 far as you're aware, follow up with ZHP
17 about this deficiency?
18 A. See, as indicated earlier
19 also, this is the process, and the DMF --
20 like agency always sending the deficiency
21 to the DMF holder, and DMF holder is
22 normally, they respond to the queries.
23 And in 2010, whether they
24 have shared this deficiencies with us or

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1 not, I'm really not aware of it.
2 Q. Okay. So if ZHP got a
3 deficiency because their valsartan
4 formation had the tendency to form
5 tertiary amines, you wouldn't have seen
6 that?
7 A. No.
8 MS. PENDLEY: Okay. Let's
9 look at LP 1535.
10 (Document marked for
11 identification as Exhibit
12 Torrent-219.)
13 MS. PENDLEY: It's
14 TORRENT-MDL2875-00124209.
15 And it will be marked as
16 Torrent Exhibit 219.
17 THE WITNESS: Just a moment.
18 BY MS. PENDLEY:
19 Q. Just let me know when you've
20 got it.
21 Do you see the e-mail?
22 A. Yes, I see this e-mail.
23 Q. Okay. We can see that this
24 e-mail -- I want to start with the second

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1 e-mail down. It is from Jenny Yang. And
2 it's from September 23rd, 2015.
3 Do you see that? Do you see
4 that date?
5 A. Yeah. Yeah.
6 September 23rd, yeah.
7 Q. Okay. And Jenny Yang is one
8 of the inspectors that Torrent uses,
9 correct?
10 A. Jenny -- this was in 2015.
11 MS. BRANCATO: Objection.
12 Foundation.
13 THE WITNESS: I'm not sure
14 whether he was third party. I'm
15 not aware of this 2015 aspect.
16 BY MS. PENDLEY:
17 Q. Okay. Do you know who Jenny
18 Yang is at all?
19 A. Jenny -- he's a -- I think a
20 third party auditor, and he does the
21 audit on behalf of Torrent.
22 Q. Okay, great. So let's look
23 at what Jenny says about ZHP. We can see
24 the subject line is audit report

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1 valsartan Huahai, right?
2 Do you see that?
3 A. Just a moment, I'm reading.
4 Q. Okay. Do you see the
5 subject line that says audit report?
6 A. I have gone through, yeah.
7 Q. I'm sorry. Is that yes?
8 A. Yeah, I've gone through the
9 mail.
10 Q. Okay, perfect. So let's
11 start at Jenny Yang e-mail. It says,
12 "The people from this manufacturer is too
13 much protective of their system."
14 Do you see that?
15 A. Yeah, I read it.
16 Q. Okay. And so this
17 manufacturer will be referencing Huahai
18 or ZHP?
19 MS. BRANCATO: Objection.
20 Foundation.
21 BY MS. PENDLEY:
22 Q. Right?
23 A. I'm not sure there, I think,
24 about which manufacturer. Just a moment.

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1 Q. Well, the subject line says
2 valsartan Huahai.
3 A. Huahai, yeah.
4 Q. So we are talking about ZHP,
5 right?
6 MS. BRANCATO: Objection to
7 foundation.
8 THE WITNESS: I'm not sure
9 if Huahai is a supplier. But it
10 is written as audit report
11 valsartan Huahai.
12 BY MS. PENDLEY:
13 Q. And Huahai is ZHP, right?
14 Is that right?
15 A. I'm trying to really
16 understand why they write Huahai and not
17 ZHP. But I'm really unsure about it.
18 Q. Okay. You as the head of
19 quality never heard ZHP referenced as
20 Huahai?
21 A. No. We have referenced this
22 sometimes that Huahai and ZHP has been
23 written in that way.
24 Q. Okay.

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1 A. But in 2015, this mail is
 2 related to ZHP or something else, I'm not
 3 confirming that. That is only reason.
 4 But I do agree we write
 5 Huahai and ZHP.
 6 Q. So you do know Huahai and
 7 ZHP. Do you know them to be the same
 8 thing? Is that what you're saying?
 9 A. I am not really sure about
 10 that 2015 audit report.
 11 Q. All right. Well, what other
 12 company involved with the production of
 13 valsartan would be referenced as Huahai?
 14 A. So maybe during the process,
 15 maybe sometimes we looked into the
 16 suppliers. And this may be a supplier
 17 program and something like that. But I'm
 18 not really sure about it.
 19 Q. Okay. Well, you're the head
 20 of quality. Shouldn't you know all the
 21 different suppliers that are being used
 22 to manufacture valsartan?
 23 MS. BRANCATO: Objection to
 24 form.

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1 THE WITNESS: So can I
 2 understand your question once
 3 again?
 4 BY MS. PENDLEY:
 5 Q. Yes. You as the head of
 6 quality, it's your job to know all the
 7 manufacturers involved in the production
 8 of valsartan, right?
 9 A. So whatever that
 10 manufacturers I'm using on the commercial
 11 basis, I'm aware of the API supplier.
 12 Q. Okay. And you're not aware
 13 of any other supplier involved in
 14 valsartan production that goes by Huahai,
 15 right?
 16 A. Since last three years,
 17 four years, what I've seen, ZHP is our
 18 supplier for valsartan.
 19 Q. Okay, great. This document,
 20 Jenny Yang is saying the people from
 21 Huahai is too much protective of their
 22 system.
 23 Do you see that?
 24 A. Yeah. I see that.

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1 Q. Protective as in secretive,
 2 right?
 3 MS. BRANCATO: Objection to
 4 form and foundation.
 5 BY MS. PENDLEY:
 6 Q. You can answer.
 7 A. So what I see is it is the
 8 manufacturer is too much protective of
 9 their system. And if anything beyond,
 10 I'm not sure.
 11 Q. All right. They go on to
 12 say, "I'm actually not satisfied with
 13 most of their reply, but I think you need
 14 to receive the conclusion early so I send
 15 the conclusion first."
 16 Okay.
 17 She goes on to say, "Anyway,
 18 I send another e-mail to them inform them
 19 that their CAPA are not acceptable."
 20 What does CAPA stand for?
 21 A. Again?
 22 Q. CAPA is corrective and
 23 preventive action?
 24 A. CAPA is corrective and

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1 preventive action.
 2 Q. Okay. So Jenny Yang is
 3 saying Huahai's CAPA is not acceptable in
 4 2015, right?
 5 A. Yeah. They have written and
 6 that's what I think they were discussing
 7 with supplier to do more to -- basically
 8 when they write CAPAs.
 9 Q. Okay. Under that, she goes
 10 on to say, "Some of their concepts were
 11 totally wrong..."
 12 Do you see that?
 13 A. Yes.
 14 Q. ...making some of Huahai's
 15 concepts that she evaluated are totally
 16 wrong.
 17 MS. BRANCATO: Objection.
 18 Foundation.
 19 BY MS. PENDLEY:
 20 Q. Have you ever seen this
 21 before?
 22 A. This mail?
 23 Q. Yes.
 24 A. No, this mail I'm looking

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1 for the first time.
2 Q. Okay. So you had never seen
3 that some of ZHP's concepts are totally
4 wrong and not patient care?
5 A. I have not seen this mail.
6 Q. Okay.
7 A. This is 2015. And
8 definitely I have not gone through this
9 mail at any time.
10 Q. So it says, "ZHP's concepts
11 are not concerned with patient care."
12 That's what the inspector is telling you
13 guys, right?
14 A. Yeah, it is written here.
15 Q. Okay. She says, "For
16 example, they just performed the
17 completely cleaning of the dryer after
18 100 batches." It goes on to say, "They
19 have no idea about degradation."
20 Do you see that?
21 A. Yeah, it is written here.
22 Q. So ZHP has no idea about
23 degradation?
24 MS. BRANCATO: Objection to

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1 foundation.
2 BY MS. PENDLEY:
3 Q. Right?
4 MS. BRANCATO: Same
5 objection.
6 BY MS. PENDLEY:
7 Q. Right? That's what it says?
8 A. So it is written here, "They
9 have no idea about degradation."
10 Q. Okay. And degradation, that
11 means like the way something breaks down,
12 right?
13 A. Yes, is based on --
14 Q. Okay. Is degradation an
15 important principle to understand in the
16 pharmaceutical industry?
17 A. You're correct.
18 Q. Okay. And so they are
19 telling you that ZHP does not understand
20 degradation, which is an important
21 principle in the pharmaceutical industry,
22 right?
23 MS. BRANCATO: Objection to
24 form and foundation.

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1 BY MS. PENDLEY:
2 Q. Right?
3 MS. BRANCATO: Same
4 objection.
5 BY MS. PENDLEY:
6 Q. You can answer.
7 A. See, what I read here is
8 written in e-mail. "They have no idea
9 about degradation." That's correct.
10 Q. All right. Now, as head of
11 quality, you would want to know about
12 that, wouldn't you?
13 A. So vendor qualification
14 program is always an ongoing process.
15 And this is not the last audit report we
16 have. And definitely, we have a much
17 more -- more -- this is in 2015. But
18 what other CAPAs they have taken, and
19 what corrections they have done after
20 several audit is being done with this
21 vendor.
22 Q. Okay. And we'll walk
23 through some of those a little bit later.
24 But at this point, as the head of

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1 quality, would you not want to know that
2 you are using an API supplier that at
3 least used to have no idea about
4 degradation?
5 A. This is 2015 status. And
6 the status is always dynamic, it changes.
7 Then based upon the current inspection
8 reports, what is dealt with with the
9 right aspect, is not of that aspect.
10 Q. Right. But they
11 manufactured valsartan API for you in
12 2015, did they not?
13 A. Yeah.
14 Q. Okay. So in 2015 while
15 they're making API for you, they have no
16 idea about degradation, right?
17 MS. BRANCATO: Objection.
18 Foundation.
19 BY MS. PENDLEY:
20 Q. Right? Mr. Jaiswal, did you
21 hear my question?
22 A. Yeah, I'm trying to really
23 understand it. But what I am able to
24 understand here is that they have

<p>Page 178</p> <p>1 indicated they have no idea about the 2 degradation and they're saying that the 3 product comply with the specification. 4 So the compliance to the 5 specification is always -- see, there is 6 a certain specification, and every batch 7 of every lot needs to be tested to meet 8 that specification level. 9 That cannot be without -- 10 without doing that, you cannot be 11 indicating that it is meeting the 12 specification or not meeting the 13 specification. 14 Q. Okay. I want to back up for 15 just a second. You know that in 16 September 2015, Torrent product with 17 valsartan API from ZHP had already made 18 its way into the U.S., right? 19 A. With ZHP, yes, our supplier, 20 and yes, we were using their API. 21 Q. Okay. And you're not aware 22 of a follow-up report to this e-mail that 23 says, you know, never mind, we're 24 changing our assessment, ZHP understands</p> <p>Page 179</p> <p>1 degradation now, right? 2 A. Which portion of the mail 3 you are referring? 4 Q. The part that we're looking 5 at, where she says they have no idea 6 about degradation. You have no 7 information, no report, no update from 8 this that says never mind, ZHP 9 understands degradation now, right? 10 A. Then follow-up of these 11 findings, there must be a follow-up 12 corrective action. And with that, 13 definitely they must have been in 14 compliance to it. And anyway we always 15 test every batch of API which is being 16 supplied to them to the specification. 17 Q. You mentioned that there 18 must be a follow-up. Well, you would 19 hope so, right, but you can't confirm 20 that you've seen one, right? 21 A. That is what I indicated. 22 This is not the last report. After this 23 also there must be several audits 24 happening. And if there is an issue with</p>	<p>Page 180</p> <p>1 the supplier, it cannot be qualified. 2 When vendor is qualified in 3 the sense that it has met all the 4 required requirements and is meeting with 5 the correct specification and guidelines. 6 Q. Okay. I'm not asking about 7 testing that Torrent was doing or 8 anything like that. 9 I'm just asking, this e-mail 10 says ZHP has no idea about degradation. 11 Did you see any follow-up 12 information to confirm that that has 13 changed? 14 A. That I need to really look 15 into, because I am not -- I've seen this 16 mail first time. And that's why whether 17 any follow-up is to be seen, I need to 18 see that. 19 Q. Right. So you're the head 20 of quality, right? 21 A. Yeah. 22 Q. Right. And you told me 23 earlier that you were definitely involved 24 in selecting API manufacturers, right?</p> <p>Page 181</p> <p>1 A. That's not in 2015. 2 Q. Right. No, but you told me 3 that is part of your job. 4 A. Yeah. Agreed. Correct. 5 Q. Okay. You told me that you 6 are involved in quality of the drugs as 7 well, right? 8 A. Yeah. It is correct. 9 Q. And so you as head of 10 quality have never seen this document 11 that says your API manufacturer has no 12 idea about degradation, right? 13 A. Yeah. This is what I'm 14 indicating. This is a 2015 status. And 15 after this report, the API supplier is 16 qualified. 17 Q. You would hope, right? It's 18 your hope that ZHP is qualified later, 19 right? 20 A. No. 21 MS. BRANCATO: Objection to 22 form. 23 THE WITNESS: No. It's -- 24 we have, like, audit done after</p>
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1 this also. And those audit
 2 reports are indicating that vendor
 3 is qualified.
 4 BY MS. PENDLEY:
 5 Q. You are aware that in 2015
 6 Torrent was relying on a statement from
 7 ZHP about genotoxic impurities, do you
 8 remember that?
 9 A. Can you repeat the question?
 10 Q. Yeah. Do you remember
 11 receiving, or are you aware that Torrent
 12 received a genotoxicity statement from
 13 ZHP in 2015?
 14 A. Yeah. As a part of
 15 declaration, yes.
 16 Q. Right. And that declaration
 17 said there are no genotoxic impurities in
 18 valsartan API, right?
 19 A. From the ZHP declaration?
 20 Q. Yes.
 21 A. There is the declaration. I
 22 have seen it.
 23 Q. Okay. And in that same year
 24 you got that declaration from ZHP saying

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1 there's nothing genotoxic in this drug,
 2 your inspector tells you they have no
 3 idea about degradation, right?
 4 A. So, I --
 5 Q. Yes or no? Same year,
 6 right?
 7 A. No. I will give a little
 8 bit of aspect here.
 9 Saying that -- for the
 10 degradation, and genotoxic impurities is
 11 not a degradation. Those are the process
 12 impurities all of this.
 13 Q. Right. But it also says
 14 that they just claim their product
 15 complies with specification. So the same
 16 year that you learned this company just
 17 claims their product complies with
 18 specification, you're relying on their
 19 statement that there's no genotoxic
 20 impurities in your drug; is that right?
 21 A. See if I'm correctly
 22 understanding. But each and every lot is
 23 being tested for -- for the agreed upon
 24 specification. And every lot is being

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1 qualified to those specification.
 2 As far as genotoxic alerts
 3 is concerned, it is always being a part
 4 of DMF and it will always being a part of
 5 assessment as being a risk being
 6 submitted in the DMF.
 7 And we always rely on that
 8 declaration, which is being submitted to
 9 agency as well as for us, because
 10 declaration is a part of DMF, and we
 11 always rely on that.
 12 Q. Okay. So that was
 13 interesting, but what I'm asking is, you
 14 rely on ZHP for the genotoxic
 15 declaration, correct?
 16 A. Yeah.
 17 Q. You're relying on ZHP's
 18 testing for the genotoxic declaration,
 19 right?
 20 A. Yeah. Agreed.
 21 Q. Yes. The same company that
 22 you were just told just claims their
 23 product complies with testing, right?
 24 MS. BRANCATO: Objection to

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1 form.
 2 BY MS. PENDLEY:
 3 Q. Is that right?
 4 A. Method of communicating,
 5 these are two different chapters, the
 6 degradation and the genotoxic results
 7 impurities. These are two different
 8 aspects.
 9 Q. Okay. I'm not asking about
 10 degradation anymore. I've switched
 11 gears. "They claim their product
 12 complies with specifications."
 13 This doesn't say which
 14 specifications. It just says
 15 specifications, any and all
 16 specifications, right?
 17 MS. BRANCATO: Objection to
 18 form and foundation.
 19 THE WITNESS: I'm not sure
 20 which specification. But whenever
 21 we say specification, it's always
 22 a set of specification which is
 23 being approved and regulated.
 24 BY MS. PENDLEY:

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1 Q. Right. And as you can see
2 from this e-mail, nobody followed up to
3 ask, "Hey, Jenny, which specifications?"
4 Right?

5 MS. BRANCATO: Objection to
6 foundation.

7 THE WITNESS: Not sure if
8 any follow-up is being done on
9 this mail.

10 BY MS. PENDLEY:
11 Q. Right. The only reply that
12 we see here is just "FYI." Right?

13 A. Yeah, because he's the
14 person who has given it to one of the
15 team member, and this person is a kind of
16 secretary and he copied e-mail to the
17 quality team.

18 Q. Okay. And you mentioned
19 that each and every lot is being tested
20 by ZHP and Torrent. Do you remember
21 that?

22 A. Yes.

23 Q. Okay. Well, we know now
24 each and every lot was not being

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1 adequately tested for genotoxic
2 impurities. We can agree?

3 MS. BRANCATO: Objection to
4 form.

5 THE WITNESS: I'm not
6 denying, because I have indicated
7 each and every lot has been tested
8 for agreed specification. And
9 agreed specification, what I'm
10 talking about is the specification
11 which has been filed within the
12 ANDA which is as per the DMF.

13 BY MS. PENDLEY:
14 Q. I'm asking specifically
15 about genotoxic impurities.

16 So we can agree each batch
17 was not being adequately tested for
18 genotoxic impurities, we can agree?

19 MS. BRANCATO: Objection to
20 form.

21 THE WITNESS: You are
22 indicating -- it is not a matter
23 of adequate testing because each
24 and every lot is being adequately

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1 tested for the specification which
2 is being approved within the ANDA.

3 BY MS. PENDLEY:
4 Q. But not for genotoxic
5 impurities, right?

6 A. Being tested for all the
7 specification as per the approved ANDA.

8 Q. Okay. But you know NDMA and
9 NDEA, two genotoxic impurities, were
10 found in valsartan's API, right?

11 A. Yeah.

12 Q. So it was obviously not
13 being tested adequately?

14 MS. BRANCATO: Objection to
15 form.

16 THE WITNESS: Because this
17 was not a part of a specification.

18 BY MS. PENDLEY:
19 Q. But it should have been,
20 right?

21 MS. BRANCATO: Objection to
22 form and foundation.

23 BY MS. PENDLEY:
24 Q. Right?

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1 Okay. Mr. Jaiswal, despite
2 this -- okay, my last question, it should
3 have -- genotoxic impurity testing should
4 have been part of the specification,
5 right?

6 MS. BRANCATO: Objection to
7 form and foundation.

8 BY MS. PENDLEY:
9 Q. Mr. Jaiswal, do you need me
10 to ask the question again?

11 A. Yeah.

12 Q. Okay. We can agree that
13 genotoxic impurity testing should have
14 been part of the specification, right?

15 MS. BRANCATO: Same
16 objections.

17 You can answer, Sushil.

18 THE WITNESS: It is not part
19 of the specification, and it was
20 not like a discovery at that
21 moment of time. It has never been
22 a part of the DMF. It would be
23 a -- like a specification within
24 like in the DMF.

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1 BY MS. PENDLEY:
2 Q. Right. But it should have
3 been?
4 MS. BRANCATO: Same
5 objections.
6 BY MS. PENDLEY:
7 Q. Right?
8 A. This, according to me, this
9 is like DMF holder is to be able to
10 answer this. Like, I'm not able to
11 answer this in that sense because I'm not
12 aware of the manufacturing process of the
13 API and that's why whether this
14 impurities is -- possibility it was there
15 or not, that is difficult to conclude,
16 because to conclude that genotoxic
17 impurities was in the API, you're
18 supposed to know the complete detailed
19 manufacturing process, including all like
20 process condition.
21 And without that, you cannot
22 be able to decide whether there is
23 such -- which impurities to be part of
24 the specification or which impurity is

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1 not part of the specification.
2 Q. Did you just read that from
3 something?
4 A. Pardon?
5 Q. Did you just read that from
6 something?
7 A. Which one?
8 Q. The answer that you just
9 gave?
10 A. No.
11 Q. Okay. As the head of
12 quality, you're telling me that you can't
13 answer whether or not genotoxic impurity
14 testing should have been part of the
15 specification?
16 A. So any --
17 MS. BRANCATO: Same
18 objection.
19 Go ahead, Sushil.
20 THE WITNESS: It depends
21 upon the API manufacturing process
22 and based upon the production
23 conditions, and say, there are --
24 let me give you a little -- more

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1 elaborate on this aspect of this
2 topic.
3 The API manufacturer, they
4 manufacture the API in the
5 different stage of manufacturing
6 process, and we call it Stage, 1,
7 2, 3, 4.
8 And throughout this process,
9 they basically clean and clean and
10 clean that substance. And within
11 the DMF, within the closed part of
12 DMF, within the restricted part of
13 DMF, this aspect, how they have
14 designed their experiment and how
15 they achieve this aspect.
16 And as an ANDA holder, we
17 never get that portion of the DMF.
18 The ANDA holder is not able to
19 understand whether -- which
20 genotoxic impurities are supposed
21 to be part of the specification.
22 This is only to be decided
23 by the API manufacturer, and once
24 they give a declaration, based

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1 upon that, ANDA holder is supposed
2 to be making this as part of the
3 specification and making it a part
4 of ANDA.
5 THE VIDEOGRAPHER: Sorry to
6 interrupt, Counsel.
7 Mr. Jaiswal, could you
8 either pull your screen towards
9 you or move up a little bit just
10 so we can position your head a
11 little better on the screen.
12 THE WITNESS: Now are you
13 able to see me?
14 THE VIDEOGRAPHER: Yes,
15 that's better.
16 BY MS. PENDLEY:
17 Q. Okay. But as the finished
18 dose manufacturer, it's also Torrent's
19 duty to follow industry standards
20 regarding genotoxic impurities, right?
21 A. Yes.
22 Q. Because you want to ensure
23 those genotoxic impurities don't end up
24 in your finished product, right?

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1 A. So, like, genotoxic
2 impurities may be generated within the
3 API also, and in the formulation also
4 based on your manufacturing process.
5 You always assess whether
6 API which you are using and the
7 excipients which you're using is -- they
8 are basically generating any kind of
9 impurity.
10 And that assessment is with
11 the ANDA holder, and with the impurity
12 coming out of the API is always with the
13 DMF holder.
14 And that always is in the
15 closed part of the DMF. And they give a
16 declaration and I think to us, to agency,
17 what are the genotoxic alerts possible in
18 their process and what is the mitigation
19 strategies they have.
20 And based upon that, we
21 always ensure to add those impurities in
22 our specification.
23 Q. Okay.
24 A. In this case --

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1 Q. Let me back up a little bit
2 because my question was a little bit more
3 simple.
4 You want to make sure
5 genotoxic impurities don't end up in your
6 finished dose, yes or no?
7 MS. BRANCATO: Objection to
8 form.
9 BY MS. PENDLEY:
10 Q. You can answer.
11 A. Can I have really --
12 understand your question once again.
13 Q. As a finished dose
14 manufacturer, you don't want genotoxic
15 impurities in your finished dose, right?
16 MS. BRANCATO: Same
17 objection.
18 THE WITNESS: So it really
19 depends upon the overall
20 manufacturing process of API and
21 formulation together. And if any
22 genotoxic impurity is there, then
23 you need to be having a control
24 strategy in place, which is part

Page 196

1 of ANDA at the time of filing.
2 And that is always being
3 discussed and assessed between the
4 FDA and API manufacturer and with
5 the ANDA holder.
6 But I'm not saying that
7 to -- like none of the product in
8 the globe is having, like, a
9 product that genotoxic alert is
10 not there.
11 BY MS. PENDLEY:
12 Q. Okay. My question was: Do
13 you want genotoxic impurities in your
14 finished dose?
15 MS. BRANCATO: Same
16 objection.
17 You can answer, Sushil.
18 THE WITNESS: I think I
19 explained that it all depends on
20 the science, chemistry, what is
21 being used for the product.
22 And based upon that,
23 basically it is being concluded
24 whether the product is supposed to

Page 197

1 be some genotoxic alert and the
2 limits.
3 And that is what is the
4 guidance available with several
5 approach that limit -- you are
6 supposed to proceed with that.
7 So, like, I'm not saying
8 that to what question is being
9 asked, answering yes or no.
10 But definitely, this is my
11 answer, that it is a scientific
12 evaluation of the API
13 specification -- API process. And
14 based on that, API impurities is
15 being agreed upon. And based on
16 the declaration of the API
17 impurities, the formulation
18 manufacturer set up their own
19 specification and includes those
20 impurities and the specification.
21 BY MS. PENDLEY:
22 Q. Okay. You're saying it
23 depends, sometimes you do want genotoxic
24 impurities in your drug?

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1 MS. BRANCATO: Objection to
2 form.
3 THE WITNESS: I'm not saying
4 that I want genotoxic impurity in
5 the product. What I'm trying to
6 say, it is a science. It is a
7 chemistry.
8 BY MS. PENDLEY:
9 Q. No, I understand that. I
10 know --
11 MS. BRANCATO: I'm sorry.
12 He's giving his answer. Let him
13 finish.
14 MS. PENDLEY: Okay. It's
15 been a little bit narrative. So
16 I'm just going to clarify my
17 question real quick.
18 BY MS. PENDLEY:
19 Q. My question was: As a
20 finished dose manufacturer, do you want
21 it in there? Not is it going to show up,
22 not how did it get there. Is it a good
23 thing to see a genotoxic impurity in your
24 drug as a finished dose manufacturer, yes

Page 199

1 or no?
2 MS. BRANCATO: Objection to
3 form.
4 THE WITNESS: And this is
5 what I'm indicating. This is an
6 answer not in a yes and no. I
7 can't answer based upon the real
8 sense of chemistry and limitation
9 of that aspect.
10 We have several product
11 molecule like a genotoxic impurity
12 is always be part of a
13 specification, as long as we
14 control. And but still it is
15 going -- because the chemistry is
16 not -- the chemistry is not able
17 to have a free of those either
18 genotoxic alerts or from the Class
19 I, Class II solvents.
20 BY MS. PENDLEY:
21 Q. Okay. Let me switch gears a
22 little bit.
23 A. I'm am sorry. Whether I
24 like or don't like, but it is supposed to

Page 200

1 go by the chemistry.
2 Q. Okay. So despite all the
3 information that we talked about earlier,
4 that you have a cheap Chinese API
5 supplier who doesn't understand
6 degradation and says their test complies
7 with specification, Torrent continues to
8 rely on ZHP to test valsartan API,
9 correct?
10 MS. BRANCATO: Objection to
11 form.
12 BY MS. PENDLEY:
13 Q. You can answer.
14 A. So I'll say, that is what --
15 if you really understand the overall
16 objective, the each and every lot, once
17 you receive at your -- and once you test
18 to the agreed specification, which
19 they -- agreed specification, I'm talking
20 about the specification which is within
21 the ANDA. And once you are testing each
22 lot to those specification, you are
23 relying to the API manufacturer alone is
24 not there, because you are testing each

Page 201

1 and every lot in your own quality system.
2 MS. PENDLEY: All right.
3 Let's look at LP 1394.
4 (Document previously marked
5 for identification as Exhibit
6 Torrent-83.)
7 MS. PENDLEY: It is
8 previously marked as Torrent-83.
9 THE WITNESS: 83. Just a
10 moment.
11 BY MS. PENDLEY:
12 Q. Okay. Whenever you've got
13 it pulled up, we can see that this is an
14 e-mail from 2014.
15 A. Just a moment.
16 Q. Okay.
17 A. Yes. Torrent-83.
18 Q. Yep.
19 A. Yes.
20 Q. So again, this is before you
21 started working at Torrent, right?
22 A. Yes.
23 Q. Okay. You mentioned to me
24 earlier the old process versus new

Page 202

1 process stuff. And you said that Torrent
2 only ever used old process in valsartan
3 U.S. product, right?
4 A. Yeah.
5 Q. Okay. So this document, I
6 want to start in the middle of the page
7 where it's from Sue Perry. And we can
8 see she asks a question. And then it
9 looks like Brijesh Patel responds to her
10 in darker blue.
11 Do you see that?
12 A. Yes.
13 Q. Let's look at her e-mail.
14 She says, "Brijesh, I have some concerns
15 with this amendment."
16 A. Can you repeat?
17 Hello?
18 Q. Let's back up a little bit.
19 So the subject of this e-mail is "CMC
20 Amendment AVH tablets"?
21 A. Yes.
22 Q. And the AVH is amlodipine/
23 valsartan/hydrochlorothiazide, right?
24 A. Yes.

Page 203

1 Q. Okay. So there's obviously
2 been amendment submitted pertaining to
3 amlodipine/valsartan/hydrochlorothiazide.
4 A. Okay.
5 Q. This e-mail says -- Sue
6 Perry from Torrent U.S. is saying, "I
7 have some concerns with this amendment.
8 Of course I haven't seen their full DMF."
9 Okay. So the full DMF would
10 be referencing ZHP's DMF, right?
11 MS. BRANCATO: Objection
12 foundation.
13 THE WITNESS: So it is not
14 written here which number. Also
15 I'm not finding. But I zoom --
16 no, in the full mail, I'm not
17 finding the DMF reference also.
18 BY MS. PENDLEY:
19 Q. Okay. But you just told me
20 that you didn't use any other API
21 supplier for valsartan aside from ZHP,
22 right, from the time that valsartan was
23 actually on the market?
24 A. That is correct.

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1 Q. She says, "I have concerns
2 with the DMF." But -- and she goes on to
3 say, "They have used different solvents,
4 but I seen nothing that indicates that
5 they tested for the DMF and MTBE and they
6 were not found." Do you see that?
7 A. Just one moment. The first
8 query, "They have used different solvent
9 but I see nothing that indicates that
10 they tested for DMF and MTBE and they
11 were not found."
12 Please refer this... and
13 absence of new solvent as well as heavy
14 metal. Attached...
15 Okay. Yeah, so what is your
16 query here?
17 Q. Okay. So Sue Perry is
18 asking Brijesh, "They," being ZHP, "have
19 used different solvents but I see nothing
20 that indicates they tested for DMF."
21 Right?
22 A. Mm-hmm.
23 Q. Is that a yes?
24 A. Yes.

Page 205

1 Q. Okay. And then we see
2 Brijesh answers her in that lighter blue
3 color that says, "Vendor has tested,"
4 right?
5 A. Okay. So I think -- say --
6 can I -- can I really define -- or can I
7 explain some of the thing? Like whenever
8 we say that there's a specification which
9 is a part of the DMF and which is being
10 agreed between agency and DMF holder, it
11 is always being done based upon some
12 rationale.
13 And for the solvent, like,
14 whatever the process -- as I indicated
15 that solvents is being used in different
16 stage of manufacturing, and based upon
17 that distribution being devised.
18 Q. Okay. I gotcha. My
19 question is just, it says, "Vendor has
20 tested." Right?
21 A. Yeah.
22 Q. And vendor would be ZHP, not
23 Torrent, right?
24 A. Yeah, vendor is definitely

<p style="text-align: right;">Page 206</p> <p>1 not Torrent.</p> <p>2 Q. Okay. So we can see that</p> <p>3 Torrent is relying on this vendor for</p> <p>4 that information that they're discussing,</p> <p>5 right?</p> <p>6 A. Yeah. Correct.</p> <p>7 Q. Okay. Then that second</p> <p>8 bullet, Sue Perry asks another question,</p> <p>9 you know, talking about the route of</p> <p>10 synthesis and intermediate remain the</p> <p>11 same and there's no change in the</p> <p>12 impurity profile.</p> <p>13 She goes on to say like, I</p> <p>14 agree -- I'm paraphrasing, obviously --</p> <p>15 but please verify that the DMF</p> <p>16 manufacturer has evaluated the impurity</p> <p>17 profile.</p> <p>18 Do you see that?</p> <p>19 A. Which question are you</p> <p>20 referring to again?</p> <p>21 Q. The second bullet point, so</p> <p>22 that whole thing is going to be Sue</p> <p>23 Perry's question to Brijesh.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 208</p> <p>1 break. But I think it's almost</p> <p>2 8:00 p.m. in India. So Sushil may</p> <p>3 want to take a quick dinner break.</p> <p>4 Sushil, what do you want to</p> <p>5 do?</p> <p>6 THE WITNESS: Yeah, I think</p> <p>7 now it is almost 7:30 India time.</p> <p>8 MS. BRANCATO: Would you</p> <p>9 like to take a break now or would</p> <p>10 you like to keep going?</p> <p>11 THE WITNESS: No, I think</p> <p>12 we'll take a break, we'll have a</p> <p>13 dinner, and then come back.</p> <p>14 MS. BRANCATO: Okay. Let's</p> <p>15 go off. Is it okay if we go off</p> <p>16 the record, Madeline?</p> <p>17 MS. PENDLEY: Yeah, let's do</p> <p>18 like 45 minutes.</p> <p>19 THE VIDEOGRAPHER: The time</p> <p>20 is now 9 -- 10 o'clock a.m. (7:30</p> <p>21 p.m. India Time.) We're going off</p> <p>22 the record.</p> <p>23 - - -</p> <p>24 (Whereupon, a dinner break</p>
<p style="text-align: right;">Page 207</p> <p>1 A. I have gone through it, yes.</p> <p>2 Q. Okay. And then the answer</p> <p>3 once again is, "Yes, the DMF holder has</p> <p>4 already provided confirmation for the</p> <p>5 same."</p> <p>6 Do you see that?</p> <p>7 A. Yeah.</p> <p>8 Q. Okay. So the DMF holder</p> <p>9 again is not Torrent, right?</p> <p>10 A. Yes. It is not Torrent.</p> <p>11 Q. That would be ZHP, right?</p> <p>12 A. Though, ma'am, the DMF</p> <p>13 number is not here. So I'm not able to</p> <p>14 conclude. But maybe. I'm not sure.</p> <p>15 Q. All right. But it's not</p> <p>16 Torrent. So Torrent is relying on</p> <p>17 somebody else for this information,</p> <p>18 right?</p> <p>19 A. Correct.</p> <p>20 Q. Okay.</p> <p>21 MS. PENDLEY: Okay. Let's</p> <p>22 go to LP 45.</p> <p>23 MS. BRANCATO: I don't know</p> <p>24 if this is a good point to take a</p>	<p style="text-align: right;">Page 209</p> <p>1 was taken.)</p> <p>2 - - -</p> <p>3 THE VIDEOGRAPHER: The time</p> <p>4 is now 10:45 a.m. (8:15 p.m.</p> <p>5 India Time.) We're back on the</p> <p>6 record.</p> <p>7 BY MS. PENDLEY:</p> <p>8 Q. Okay. Mr. Jaiswal, I want</p> <p>9 to look at LP 45 with you. One second,</p> <p>10 I'll give you the exhibit number. Going</p> <p>11 to be Torrent Exhibit 218.</p> <p>12 A. Yes, Torrent-218.</p> <p>13 THE VIDEOGRAPHER: Counsel,</p> <p>14 it looks like we have a 218. 219?</p> <p>15 MS. PENDLEY: No, we're</p> <p>16 going back to a document that</p> <p>17 we've already used.</p> <p>18 THE VIDEOGRAPHER: I</p> <p>19 apologize.</p> <p>20 MS. PENDLEY: No, you're</p> <p>21 fine.</p> <p>22 BY MS. PENDLEY:</p> <p>23 Q. I want to start at the</p> <p>24 bottom of the first page. We see this is</p>

Page 210

1 an e-mail from you, right?

2 A. Yeah.

3 Q. Okay. And you send this on

4 August 28th, 2018. And you start by

5 saying, "The vendor," ZHP, "has provided

6 a declaration on October 9th, 2009, that

7 in their drug either doesn't have

8 genotoxic impurities or they are under

9 the levels."

10 Do you see that?

11 A. Are you referring to the

12 mail?

13 Q. I'm referring to -- yes, the

14 e-mail, that paragraph at the bottom of

15 the page. I'm looking at the first

16 sentence.

17 Do you see that?

18 A. Yeah, I'm just trying to

19 read the mail. The mail you're referring

20 to the top mail or the bottom?

21 Q. Yes, the paragraph at the

22 bottom.

23 A. Yeah.

24 Q. Okay. So you say, ZHP gave

Page 211

1 you, Torrent, a declaration saying

2 there's no genotoxic impurities in the

3 drug, right?

4 A. I'm trying to see that

5 portion of letter.

6 Q. Do you see what I'm talking

7 about?

8 A. Yeah, give me just a moment.

9 You're referring to the

10 first sentence? "In 2013, API

11 manufacturer proposed an alternative

12 process, which is identified by the" --

13 and that is the sentence that you're

14 referring to me?

15 Q. No. Back up just a little

16 bit. It's on the first page at the

17 bottom. There's a paragraph. And if you

18 need to not look at the document that

19 you've downloaded, just look at the Zoom

20 screen --

21 A. Yeah.

22 Q. -- the trial tech has the

23 document, and he's highlighting where we

24 are, if that helps.

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1 Do you see that?

2 A. Yeah, I see it.

3 Q. Okay. So you're with me

4 now. Bottom of Page 1.

5 Okay. So Torrent didn't

6 actually test the API for genotoxic

7 impurities in 2009, right?

8 A. Yeah, correct.

9 Q. Okay. Now in 2013 -- go to

10 the next page. This is where you were

11 before.

12 It says the API manufacturer

13 changed their process and started using D

14 code that you told me about earlier,

15 right?

16 A. Yeah.

17 Q. Okay. When they made the

18 process change, they again provided you a

19 similar declaration as they did in 2009,

20 right?

21 A. Yeah. And it is also

22 written, "API manufacturer provide the

23 declaration that the API is free from

24 genotoxic impurity and complies to ICH

Page 213

1 M7."

2 Q. Right. Okay. So from 2009

3 to 2013, Torrent wasn't testing the API

4 for genotoxic impurities, right?

5 A. Yeah.

6 Q. Okay. You mentioned 2015.

7 They gave you another genotoxic impurity

8 statement.

9 And at this point, 2015,

10 Torrent also was not testing the API for

11 genotoxic impurities, right?

12 A. Yeah, because throughout

13 this process, the manufacturers had

14 already indicated that the API is free

15 from the genotoxic alerts.

16 Q. Right. Okay. So if you

17 remember, we looked at this e-mail from

18 Jenny Yang before, right? Do you

19 remember that?

20 A. Yeah.

21 Q. Okay. And that was from

22 2015, right?

23 A. Yes. September 2015.

24 Q. Okay. Okay. So despite

Page 214

1 learning that this company that's telling
2 you there's no genotoxic impurities in
3 your drug also has no idea about
4 degradation and stuff, you guys still
5 weren't testing the API, right?
6 MS. BRANCATO: Objection to
7 form.
8 THE WITNESS: I think I have
9 already clarified. The genotoxic
10 impurity, the process impurity, is
11 based upon the chemistry. And the
12 degradation product result is a
13 different aspect.
14 The degradation product is
15 always being monitored through the
16 testing method. And for the
17 genotoxic impurity, if it is
18 there, it has to be -- for that,
19 method is to be there in place.
20 But this genotoxic alerts is
21 always being -- like, throughout
22 the DMF process, vendor has
23 already given a claim that it is
24 meeting the ICH M7 requirement.

Page 215

1 BY MS. PENDLEY:
2 Q. Okay. But despite learning
3 that your inspector had concerns about
4 your API manufacturer, you still did not
5 confirm the testing they were giving you
6 about genotoxic impurities; is that
7 right?
8 MS. BRANCATO: Objection to
9 form.
10 THE WITNESS: No, I think --
11 I think I'm not fully in
12 agreement, because those are the
13 findings what you have seen in
14 2015 report, the citation, those
15 are not relating to the genotoxic
16 part, they are relating to the
17 degradation impurities. And
18 genotoxic impurity is not a
19 degradation impurity.
20 BY MS. PENDLEY:
21 Q. Okay. Right. But Jenny
22 Yang told you guys that she has concerns
23 about ZHP, says they're not concerned
24 with patient safety, and they have no

Page 216

1 idea what they're doing when it comes to
2 cleaning of equipment.
3 Despite that information,
4 you guys were not testing ZHP's API for
5 genotoxic impurities, right?
6 MS. BRANCATO: Objection to
7 form.
8 THE WITNESS: So again, I
9 will -- I will answer the same
10 thing, that genotoxic impurities,
11 the process impurity is purely
12 within a chemistry evaluation.
13 And the degradation
14 impurities are always different
15 impurity.
16 So these two things are not
17 correlated, and what we have seen,
18 we have seen that it went.
19 What has happened after that
20 is not being seen here.
21 And we need to really look
22 into that as well, what corrective
23 actions they are taking up after
24 this.

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1 BY MS. PENDLEY:
2 Q. And you also saw in that
3 2015 document that their corrective
4 actions were not sufficient in 2015,
5 right?
6 MS. BRANCATO: Objection to
7 form.
8 THE WITNESS: No, it's not
9 right because that is the mail
10 what we have seen is just sorted
11 out. And after that, always when
12 they do their corrective actions,
13 and based upon that, vendor is to
14 be re-evaluated always.
15 BY MS. PENDLEY:
16 Q. Okay. I want to talk to you
17 about one more date. Do you see the
18 June 20, 2018? Second paragraph. It
19 says the notification was received from
20 ZHP.
21 So this is when ZHP told
22 Torrent that a genotoxic impurity is in
23 valsartan, right?
24 A. Yeah. This is the first

Page 218

1 notification.

2 Q. Okay. Now you told me at

3 the beginning of this deposition that

4 genotoxic impurities in pharmaceutical

5 products should be taken very seriously,

6 right?

7 MS. BRANCATO: Objection to

8 form.

9 THE WITNESS: Right. And I

10 think I already indicated that a

11 genotoxic alert within the product

12 is to be always quantified, and

13 based upon that, we decide whether

14 the alert is to be -- to be taken

15 into that account, because every

16 genotoxic alert has some limits to

17 it.

18 BY MS. PENDLEY:

19 Q. Okay. Right. Just like you

20 said, every genotoxic alert should be

21 investigated, so that it can be

22 quantified, right?

23 MS. BRANCATO: Objection to

24 form.

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1 THE WITNESS: I think that

2 there's a different way around.

3 Every genotoxic alert is to be

4 investigated, what is the

5 quantification of it.

6 The only notification -- the

7 notification that it has a

8 genotoxic alert is not sufficient.

9 You're supposed to know what

10 genotoxic alert and then what is

11 the quantification and what is the

12 limit.

13 BY MS. PENDLEY:

14 Q. Okay. So Torrent gets a

15 notification there is a genotoxic

16 impurity in their drug, but they don't

17 have to investigate it yet because you

18 don't know how much?

19 A. No. Because the analysis,

20 the first thing that you're supposed to

21 know, the specification, what are like

22 the which genotoxic alert this is,

23 because there's thousands of impurities.

24 Q. Right.

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1 A. And unless you don't know

2 that, you cannot be assigning a level to

3 it. But back to the assessment of which

4 API it is -- or which genotoxic alert it

5 is, it is always to be done by the person

6 who is owning the process. And it is

7 definitely the DMF holder.

8 Q. So you're saying it's up to

9 ZHP to figure out which genotoxic

10 impurity is in the drug that you're

11 selling, right?

12 A. No. They are supposed to

13 tell us which genotoxic impurity is

14 there, in the API.

15 Q. Right, in the drug that

16 you're selling, right?

17 A. No. We are selling the drug

18 product. So we need to know what

19 impurity in the drug substance from the

20 API manufacturer.

21 Q. Right. Okay. What if ZHP

22 can't figure it out? Would Torrent test

23 it then?

24 MS. BRANCATO: Objection to

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1 form.

2 THE WITNESS: No. I'm not

3 able to understand your question.

4 BY MS. PENDLEY:

5 Q. Okay. So you, as the head

6 of quality, are telling me API

7 manufacturer learns there is a genotoxic

8 impurity in the API that you use in your

9 finished dose, right? You're telling me,

10 Torrent would not test the API to help

11 figure out what the genotoxic impurity

12 was?

13 MS. BRANCATO: Objection.

14 Form.

15 THE WITNESS: No, I think

16 this is not, like, my argument --

17 my agreement to that. Like, any

18 manufacturer, I'm not saying that

19 in company -- any manufacturer is

20 to test that until unless it is

21 not known which impurity it is.

22 The only genotoxic alert is

23 a very generic name, category.

24 You're supposed to know the

Page 222

1 real compound, what it is.
2 And without that, you cannot
3 devise your testing method.
4 Without that, you cannot be
5 devising a limits to it.
6 You cannot apply ICH M7
7 without knowing that.
8 BY MS. PENDLEY:
9 Q. So it's ZHP's job to figure
10 out which genotoxic impurity is in the
11 API?
12 MS. BRANCATO: Objection to
13 form.
14 BY MS. PENDLEY:
15 Q. Right?
16 A. I'm not able to understand
17 your question.
18 Q. What you're telling me is
19 it's ZHP's job to figure out which
20 genotoxic impurity is in the API?
21 MS. BRANCATO: Same
22 objection.
23 THE WITNESS: Definitely I'm
24 not saying that is a ZHP job. But

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1 ultimately the knowledge of the
2 chemistry lies with the DMF
3 holder.
4 BY MS. PENDLEY:
5 Q. All right. So what you've
6 just told me -- you're kind of going
7 around and around a little bit. So let's
8 start over.
9 You've told me that Torrent
10 can't test until ZHP tells them what they
11 are testing for. And I'm asking, is it
12 ZHP's job to figure out the impurity.
13 And then you say no.
14 So whose job is it to figure
15 out which impurity is in the API?
16 A. I'm not saying it is not
17 ZHP's job. What I'm saying, the DMF
18 holder is knowing the chemistry. And he
19 only is able to assign that aspect, what
20 is the impurity in their drug substance.
21 Q. Okay. So only ZHP can
22 identify the genotoxic impurity because
23 they know the chemistry?
24 Okay. So until ZHP tells

Page 224

1 Torrent --
2 THE COURT REPORTER: I
3 didn't get a verbal answer. I'm
4 sorry. He shook his head. He
5 only shook his head, though.
6 There was no verbal.
7 BY MS. PENDLEY:
8 Q. Okay. So the question that
9 I asked was only ZHP can identify the
10 genotoxic impurity because they know the
11 chemistry.
12 You can answer, Mr. Jaiswal.
13 A. The chemistry in the sense
14 that I'm talking about the manufacturing
15 process of the valsartan, because as a
16 drug substance -- drug product
17 manufacturer, we were not knowing how the
18 API is being manufactured, what are the
19 temperature condition, what are the other
20 conditions. It is knowledge that only
21 DMF holder.
22 And that's right. It is
23 basically their assessment. They're able
24 to only figure out what is the impurity

Page 225

1 in the drug substance.
2 Q. So you are waiting on ZHP to
3 identify the impurity, right, because
4 they know the chemistry?
5 A. Yeah, because they know the
6 chemistry.
7 Q. Okay. So from the time ZHP
8 tells you guys there is a genotoxic
9 impurity in their drug, it is only about
10 a week until ZHP tells them that
11 genotoxic impurity is NDMA.
12 Does that sound about right?
13 A. Yeah, I think. I'm not sure
14 about the date, but yes, they indicated
15 after some time it is NDMA.
16 Q. Okay. So in the meantime,
17 from the time that you learned there's a
18 genotoxic impurity in the API, to the
19 time that you find out what the impurity
20 is, what if anything is Torrent doing to
21 get control of this situation?
22 A. Like, if I'm able to
23 understand your question, you're
24 indicating that, when they are giving the

Page 226

1 first indication that there is some
2 genotoxic impurity in API, and when they
3 are giving the second information that
4 this is the, like, NDMA impurity, what is
5 being done in between?
6 This is what is question?
7 Q. Yes.
8 A. Yeah, because this
9 information, the piece of information
10 they have indicated, the first
11 information that was basically -- that
12 indicated that it is only a genotoxic
13 alert, you are not even knowing which
14 impurity it is. And that also, on the
15 precaution ground, all the supplies is
16 being put under hold.
17 Q. Okay. So valsartan product
18 is on hold between the 20th and the 26th?
19 A. Yes.
20 Q. Okay. Is it being tested by
21 Torrent at this point for genotoxic
22 impurities?
23 A. Because we are not knowing
24 which impurity, yeah.

Page 227

1 Q. All right.
2 A. So no.
3 Q. That's okay. Okay. Okay.
4 And when they finally did tell you what
5 was in the valsartan, ZHP told Torrent
6 NDMA is only in the new process, that's
7 what they initially told you guys, right?
8 A. Yeah.
9 Q. All right. That would mean
10 there's no NDMA in the old process,
11 right?
12 A. Mm-hmm.
13 Q. Is that a yes?
14 A. Yes.
15 Q. Which is what Torrent was
16 using, right, only old process?
17 A. Yeah.
18 Q. So at this point, Torrent
19 thinks its product is not contaminated
20 with NDMA; is that fair?
21 A. Yeah, once they indicated
22 that it is only a new ROS, and the old
23 process is not impacted, yes, it's fair
24 to believe that is -- old process is not

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1 impacted.
2 Q. Okay. So based on this
3 information from ZHP, Torrent gets their
4 product, old process valsartan, put back
5 on the market, right?
6 MS. BRANCATO: Objection to
7 form.
8 THE WITNESS: We
9 communicated with the FDA and we
10 have given a complete information
11 to FDA as well, indicating that
12 the DMF holder has indicated the
13 new ROS is only impacted, and
14 there is no impact on the old
15 process.
16 And with this information we
17 basically requested FDA also to
18 give us their advice, go back to
19 market, or we can hold.
20 And FDA, they have given us
21 a clarity and clearance to go to
22 the market with the old process
23 batches.
24 BY MS. PENDLEY:

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1 Q. Okay. So to simplify that a
2 little bit. Yes, after ZHP told you your
3 product wasn't implicated, you got it put
4 back on the market, right?
5 A. Yeah. But I cannot be like
6 leaving those in between assessment
7 because that is important because the
8 regulator is always supposed to be taken
9 into account while doing -- while you're
10 dealing with such kind of situation. You
11 have to take advice of your regulator as
12 well before it is called.
13 Q. Okay. So you took
14 information that ZHP gave you, and you
15 gave it to the FDA. And they let you put
16 your product back on the market, right?
17 A. Not only the information
18 sharing. It is a kind of discussion
19 happened. It is just not information.
20 It is basically inform, and then
21 basically we have taken a clearance from
22 them.
23 So it is -- information is
24 one-sided information. And once we see

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1 that, we inform them and taken their
2 consensus and approval to proceed with
3 the market.
4 Q. Sure. The information that
5 was exchanged was ZHP told us there's
6 nothing in here, the FDA says okay,
7 sounds good, and it gets back on the
8 market, right?
9 A. Yes.
10 MS. BRANCATO: Objection to
11 form.
12 BY MS. PENDLEY:
13 Q. Okay. And that information
14 was based on testing that ZHP had
15 conducted, right?
16 A. This information is based
17 upon the ZHP declaration to us. And
18 once -- I firmly believe that ZHP, once
19 this declaration giving to us, the same
20 declaration, they must be giving to FDA
21 as well as a DMF holder.
22 Q. To confirm, Torrent did not
23 test their product at this point for
24 genotoxic impurities, right?

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1 MS. BRANCATO: Objection to
2 form.
3 THE WITNESS: As already
4 indicated, till this time, we were
5 not given the name of the
6 impurity.
7 BY MS. PENDLEY:
8 Q. Well, no, let me back up
9 because you already told me by this time
10 you did know the name of the impurity.
11 ZHP told you there's nothing in the old
12 process. And you guys did not test it to
13 confirm that, correct?
14 A. In the old process?
15 Q. Right. You did not test to
16 confirm there's no NDMA in the old
17 process before putting it on the market?
18 A. Yeah, because the DMF holder
19 has given a declaration to you, and it is
20 basically -- I mean, I'm telling you that
21 the genotoxic alerts, being a process
22 impurity of the API, it is always a DMF
23 holder has to give a declaration and give
24 us a clarity whether the API has a

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1 process impurity in it or not.
2 Q. I know. I understand that
3 you want to say all that. But the answer
4 to my question is just no, we didn't test
5 the product before putting it on the
6 market, right?
7 MS. BRANCATO: Objection to
8 form.
9 THE WITNESS: This --
10 BY MS. PENDLEY:
11 Q. Not as to why. But to
12 clarify, you didn't test it, Torrent did
13 not test it?
14 MS. BRANCATO: Same
15 objection.
16 THE WITNESS: So there are
17 few answers. I cannot be giving
18 you mainly yes or no.
19 With yes, I'll also give you
20 justification.
21 And no, I will also give you
22 my justification.
23 BY MS. PENDLEY:
24 Q. Okay. No, it wasn't tested

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1 by Torrent, right?
2 MS. BRANCATO: Same
3 objection.
4 BY MS. PENDLEY:
5 Q. You can answer.
6 A. So this is what again I
7 indicated. Being a process impurity,
8 being a genotoxic alert coming up with
9 the API, the DMF holder declaration was
10 important.
11 Q. Okay. You understand that
12 once Torrent's finished dose valsartan
13 product went back on the market, that
14 means people could start taking it again,
15 right?
16 MS. BRANCATO: Objection to
17 form.
18 THE WITNESS: See, because
19 once we see it is -- we are given
20 clearance to go to the market, I
21 am not sure what is being sold and
22 who is taking it because that I
23 cannot see.
24 BY MS. PENDLEY:

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1 Q. Okay. Let me rephrase. If
2 it's on the market, it's not off the
3 market, right? It had not yet been
4 recalled?
5 A. Yeah, yeah, not recalled.
6 Q. Okay. So people can still
7 buy it?
8 A. Definitely, but I'm not able
9 to comment on that whether people were
10 buying it or people were not buying it.
11 Q. Okay. I know that. They
12 were able to buy it, is the question, I
13 guess. Okay?
14 So -- okay. At this point,
15 Torrent knows that the genotoxic impurity
16 is NDMA. So why not just develop a test
17 before releasing it back to the market?
18 A. I think API manufacturer has
19 very clearly indicated that NDMA
20 impurities there in the new process.
21 Q. Right. But they were wrong,
22 weren't they?
23 A. Pardon?
24 Q. ZHP was wrong about NDMA not

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1 being in old process, right?
2 A. Yeah. That is the follow-up
3 and incremental information.
4 Q. Right. And so looking back,
5 at the time, you guys knew what the
6 impurity was, and you knew it was in some
7 form of valsartan API. Why couldn't you
8 have just developed a test before putting
9 it back on the market?
10 A. This is what I already
11 indicated. Because the DMF holder has
12 given it with clarity the D process, the
13 new ROS is impacted, and C process is
14 free from this impurity.
15 Q. All right. Did anything
16 prevent you from deciding to develop a
17 test, because there's some rule that says
18 no, no, finished dose manufacturers can't
19 test for genotoxic impurities?
20 MS. BRANCATO: Objection to
21 form.
22 THE WITNESS: This
23 assessment, whether this impurity
24 is there in the -- your API, is --

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1 the API is a very scientifically
2 assessment of the route of
3 synthesis process.
4 And based upon that, only
5 somebody who declare that whether
6 my API has this impurity or not,
7 this information, that route of
8 synthesis is only -- only
9 available to ZHP.
10 BY MS. PENDLEY:
11 Q. Well, let me get some more
12 info on something, because we actually at
13 the beginning of this deposition looked
14 at testing levels by Torrent of ZHP's API
15 for NDMA.
16 Do you remember that?
17 A. Yeah.
18 Q. So Torrent was clearly able
19 to develop a test for NDMA at some point.
20 You would agree?
21 A. Yeah. That's correct.
22 Q. Okay. So what prevented
23 them from developing that test back in
24 June of 2018 before they put the drug

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1 back on the market?
2 A. So the development of these
3 methods needs a lot of time, resources,
4 and knowledge from the DMF holder.
5 And --
6 Q. Okay. So it takes a lot of
7 time --
8 MS. BRANCATO: Madeline, I'm
9 sorry. You've interrupted him,
10 like, three times in a row. So
11 please let him finish his answer.
12 MS. PENDLEY: I'm trying to
13 guide him back to the point of my
14 question, save some time.
15 BY MS. PENDLEY:
16 Q. How long would it take to
17 develop a test like that?
18 A. This is what I'm coming
19 into. You cannot be developing a method
20 of your own, in general, because you need
21 to always ensure that your method is
22 always aligned to the DMF manufacturer --
23 the DMF holder method.
24 And that is what our series

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<p>1 with DMF holder that is supposed to share 2 all the methods, all the related 3 information so that we will follow the 4 same method which the DMF holder is doing 5 and is supposed to submit to agency as 6 well.</p> <p>7 And as an ANDA holder, 8 because we give it over to the agency to 9 assess the DMF, we're supposed to follow 10 the same analytical method which the DMF 11 holder is using.</p> <p>12 So this is the first 13 principle I'm supposed to follow while -- 14 while using any analytical method.</p> <p>15 Q. So you're saying that 16 Torrent Pharmaceuticals, that produces 17 hundreds of different drugs, sells them 18 all over the world, is not capable of 19 coming up with a test for a carcinogen 20 without relying on the DMF holder?</p> <p>21 MS. BRANCATO: Objection to 22 form.</p> <p>23 THE WITNESS: So my answer 24 is not at all connected to this.</p>	<p>1 between two method, because you cannot 2 have your own method without doing the 3 equivalency with the DMF method until and 4 unless you don't have a DMF method at 5 all. You may not be able to develop a 6 current method as well.</p> <p>7 You're supposed to know 8 whether -- which technique they are 9 using, if they are using a GC, and if I'm 10 bringing it on HPLC, then I cannot be 11 able to do equivalency between two 12 method.</p> <p>13 Q. I --</p> <p>14 A. And this is what FDA -- this 15 is what FDA has published, several method 16 related to genotoxic alerts, and at the 17 bottom, every time they write, if you 18 have a different method, you need to 19 prove the equivalency with the FDA method 20 as well.</p> <p>21 Q. Okay. Got it. But like you 22 told me, it is a preference to rely on 23 the DMF holder, right?</p> <p>24 A. Pardon?</p>
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<p>1 So we also manufacture several 2 APIs, and we develop several 3 methods and we do develop methods.</p> <p>4 But the rule is I need to 5 follow the DMF method, which is in 6 the DMF, and I need to follow 7 that.</p> <p>8 BY MS. PENDLEY: 9 Q. Okay. We can agree there's 10 no law or rule that says you as the 11 finished dose manufacturer has to use the 12 same test as the DMF holder, right?</p> <p>13 A. That is always the first 14 preference.</p> <p>15 Q. Right. It's a preference, 16 but it's not a requirement, right?</p> <p>17 A. Yeah, it's correct.</p> <p>18 Q. Okay. So if you wanted to, 19 you could have started developing your 20 own method, could you not?</p> <p>21 A. You can -- you can develop 22 it. I'm not denying that. But it is 23 always -- not only the development 24 method, then basically to the equivalency</p>	<p>1 Q. Like you just told me, it is 2 not a requirement, but rather a 3 preference to rely on the DMF holder for 4 this test?</p> <p>5 A. So I'm really going back to 6 my statement. I very clearly indicated 7 that it's always a preferred one --</p> <p>8 Q. Right.</p> <p>9 A. -- because we are supposed 10 to prove the equivalency with the DMF 11 method until and unless -- until and 12 unless the DMF holder is --</p> <p>13 Q. Why can't Torrent --</p> <p>14 MS. BRANCATO: Madeline, 15 please stop interrupting the 16 witness. That's improper. And 17 he's allowed to finish his 18 responses. And then you can ask 19 him questions.</p> <p>20 MS. PENDLEY: Okay. You had 21 paused. And so I thought he was 22 finished. It's just a 23 miscommunication.</p> <p>24 MS. BRANCATO: A</p>

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1 miscommunication that's happened
2 now at least five times in a row.
3 MR. NIGH: Just going to be
4 clear that he trails off. We've
5 been talking about him trailing
6 off and his volume. We can see on
7 the video that that happens. And
8 there's pauses and it picks it up.
9 They're trying to do the
10 best they can if that happens. So
11 the constant interruption to say
12 that she's interrupting is just
13 improper.
14 Let her ask her questions
15 instead of laying an improper
16 record. We have a video of this
17 where we can see it.
18 MS. BRANCATO: I would ask
19 that she allow my witness to
20 finish his answers. And I will
21 allow her to finish her questions.
22 BY MS. PENDLEY:
23 Q. Okay. So who at Torrent, if
24 you know, was tasked with developing a

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1 method to test for NDMA and NDEA?
2 A. So we have our analytical
3 development team and basically they have
4 the primary responsibility to develop the
5 analytical method.
6 Q. All right. Who oversees the
7 analytical development team?
8 A. Who?
9 Q. Yes. Do you know who
10 oversees that team?
11 A. So analytical development
12 team comes under there's the analytical
13 development head. It is known as Nilesh
14 and he basically is responsible for
15 development of analytical method.
16 Q. Are you involved in
17 overseeing the analytical development
18 team?
19 A. No.
20 Q. Do they report to anybody in
21 the quality department?
22 A. No. Analytical development
23 team, they're not reporting to the
24 quality department.

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1 Q. Okay. So you have nothing
2 to do with the development of the tests
3 for NDMA or NDEA?
4 MS. BRANCATO: Objection to
5 form.
6 THE WITNESS: The
7 development team reports to
8 somebody else, not to me.
9 BY MS. PENDLEY:
10 Q. Okay. So how long did it
11 ultimately take Torrent to come up with
12 this test for NDMA and NDEA? Well, let's
13 do NDMA first. How long did it take
14 Torrent to come up with a test for NDMA?
15 A. So this NDMA impurity was
16 not common before this discovery. And
17 for the development of any test method,
18 you need a impurity in hand in order to
19 develop a method.
20 And once this impurity has
21 not been in the Pharmacopeia, the
22 Pharmacopeia as well was not developed.
23 Well, that's why first you
24 have to synthesize the impurity before

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1 you go ahead and develop the analytical
2 method.
3 Q. Okay. So like three weeks,
4 four weeks? What are we talking?
5 A. So for this method, we took
6 almost, to me, according to me, the
7 synthesis of impurity and development is
8 I think somewhere around five weeks.
9 Q. All right. So it took you
10 five weeks to develop the test. How much
11 does it cost to run a test like that?
12 A. Cost of?
13 Q. Did it cost you anything?
14 A. No, I'm not able to I think
15 tell you that because I'm not aware of
16 the cost, what is the cost.
17 Q. Okay. So we're going to
18 back up, back at the time Torrent was
19 informed NDMA is in valsartan product, it
20 would have taken you guys about five
21 weeks to come up with that test, right?
22 A. Yes, I'm telling you the
23 approximate number, five weeks.
24 Q. Right. So why didn't

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<p>1 Torrent just keep the product off the 2 market until that test was developed? 3 A. So this is decisionmaking 4 process, I will repeat -- tell you it is 5 based on the declaration, what you 6 receive from the DMF holder. And that is 7 what the DMF holder had very clearly 8 indicated, that the C code API is free 9 from this impurity. 10 Q. Okay. So before you are 11 going to expose your patients with a drug 12 with a carcinogen in it, Torrent did not 13 bother to test it, right? 14 MS. BRANCATO: Objection to 15 form. 16 THE WITNESS: I don't 17 understand your question. 18 BY MS. PENDLEY: 19 Q. Before Torrent exposes its 20 patients to a drug with a carcinogen in 21 it, it did not bother to test it before 22 putting it back on the market, right? 23 MS. BRANCATO: Same 24 objection.</p>	<p>1 A. I'm answering the same 2 question. 3 Q. Did Torrent test for NDMA, 4 yes or no? 5 MS. BRANCATO: Objection to 6 form. 7 BY MS. PENDLEY: 8 Q. What was the first part of 9 your answer? 10 A. This wasn't part of the 11 specification. 12 Q. So no, right? 13 A. See, I'm indicating this was 14 not part of the specification, and 15 product is being tested fully to that 16 specification, whatever is available. 17 Q. Okay. So can we agree that 18 nothing would have prevented Torrent from 19 just holding onto the product until they 20 confirmed there's no NDMA in it? 21 A. But there is a reason to 22 believe that the DMF holder has given a 23 declaration, the API is free from 24 impurity, then there's no reason to test</p>
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<p>1 THE WITNESS: No, I think 2 really, I'm not able to answer 3 this question because I think it 4 is not really likely indicated. 5 BY MS. PENDLEY: 6 Q. Okay. We just walked 7 through that every batch, all 119 8 batches, were contaminated with NDMA. Do 9 you remember that? 10 A. Yeah. We have seen that 11 data. 12 Q. Right. And we confirmed 13 that NDMA is a carcinogen, right? 14 A. I think we agree this was 15 discussed as well. 16 Q. Right. And so before 17 putting all of those batches back on the 18 market, just to confirm, Torrent did not 19 test it for NDMA, yes? 20 A. As I've indicated, Torrent 21 has the obligation to test the product as 22 per the approved ANDA, and we tested the 23 product to that compliance. 24 Q. That's not what I asked.</p>	<p>1 it. There's no reason to hold it, until 2 and unless it was not cleared, we hold 3 every batch. 4 Q. Okay. My question was, 5 nothing would have prevented Torrent from 6 just holding onto it until they confirmed 7 there is no NDMA through testing the 8 drug? 9 A. That is a common thing, say, 10 when -- on the first notification, on 11 26th, when they are not indicated 12 which -- whether C code or D code is 13 impacted. They give a generalized 14 statement, Torrent held every batch into 15 the market. 16 The D -- indicated that C 17 code is not impacted, then only we gone 18 back into the market. But that 19 definitely, Torrent actions was very, 20 very, like, proactive, very right, 21 looking to the data which is being 22 provided by the DMF holder. 23 Q. Okay. Well, let me back up, 24 because it obviously wasn't very right.</p>

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1 There was NDMA in that product you put
2 back on the market, right?
3 A. Again, that is in terms of
4 the analytical development.
5 Q. I feel like we're still not
6 getting an answer to the question that
7 I'm asking. Did anything prevent
8 Torrent, any rule, any law, your boss
9 telling you not to, did anything prevent
10 Torrent from just holding onto the
11 product until they, Torrent, confirmed
12 there is no NDMA in C batches?
13 A. See this is what I'm
14 indicating, I cannot be holding anything
15 where my DMF holder has very clearly
16 indicated that this API which I'm using
17 in the product is free from the genotoxic
18 alert which they have identified in D
19 ROS.
20 MS. PENDLEY: Okay. We're
21 going to move to certify the
22 question as nonresponsive.
23 MS. BRANCATO: Objection.
24 BY MS. PENDLEY:

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1 Q. You mentioned that it took
2 about five weeks to develop this test.
3 Okay. So if Torrent had held their
4 product, they had held their C batches,
5 it would not be on the market for about
6 five weeks, right?
7 A. No, I'm not able to
8 understand your question.
9 Q. Okay. If Torrent continued
10 to hold their product, it's obviously not
11 on the market, right? Let's start there.
12 A. Yeah, okay.
13 Q. Okay. And all that time
14 that Torrent is holding their product off
15 of the market, they can't sell it, right?
16 A. Ma'am, I'm not really able
17 to understand your question. I'm so
18 sorry, but I'm not able to understand
19 your question.
20 Q. Torrent was ready to put its
21 product back on the market so it didn't
22 continue to lose money, correct?
23 MS. BRANCATO: Objection to
24 form and foundation. Outside the

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1 scope of the 30(b)(6).
2 BY MS. PENDLEY:
3 Q. You can answer.
4 A. So like, see, in the
5 decisionmaking process, I'm holding those
6 decisions. I never see -- and I have
7 indicated every time we have this
8 discussion, I was not knowing that.
9 But this is purely technical
10 call based upon the assessment of the
11 database, based on the assessment of the
12 DMF holder, what declaration they have
13 given.
14 Q. So the decision to put the
15 product back on the market had nothing to
16 do with the money y'all would lose in the
17 meantime?
18 MS. BRANCATO: Objection to
19 form and foundation. Outside the
20 scope.
21 BY MS. PENDLEY:
22 Q. You can answer.
23 A. So as I indicated, once --
24 I'm not owner in the business. I'm not

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1 involved in the commerce. Then
2 definitely, I'm not able to tell you --
3 that kind of aspect is being involved in
4 the decisionmaking process.
5 MS. PENDLEY: All right.
6 Let's see about that. Let's look
7 at LP 1096.
8 THE WITNESS: Which one?
9 MS. PENDLEY: LP 1096. I'll
10 let you know the exhibit number in
11 one second.
12 (Document marked for
13 identification as Exhibit
14 Torrent-23.)
15 BY MS. PENDLEY:
16 Q. Torrent-23.
17 A. Torrent-23 is not there in
18 the list.
19 THE VIDEOGRAPHER: You might
20 have to refresh. I just added it.
21 THE WITNESS: Just a moment.
22 Yeah.
23 BY MS. PENDLEY:
24 Q. Okay. So looking at the

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1 first page -- do you see the first page?
2 A. Just a moment. Okay.
3 Q. Right. So looking at the
4 first page, let's start with the e-mail
5 from Dawn Chitty kind of towards the
6 bottom.
7 It's from Tuesday, July 17,
8 2018. It says, "The FDA is expecting
9 that we're going to prove there's no NDMA
10 in the API batches that we've used."
11 Do you see that?
12 A. Which mail are you referring
13 to?
14 Q. It's the third little set of
15 e-mails on the first page.
16 A. It is on the first page?
17 Q. Yep.
18 A. That is on the 18th of July.
19 Q. 17th. Yeah.
20 A. Okay.
21 Q. All right. She says, "FDA
22 is expecting that we're going to prove
23 there's no NDMA in the API batches that
24 we've used." Right?

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1 Do you see that?
2 A. Yeah.
3 Q. Okay. She goes on to say,
4 the statements from the vendor are not
5 sufficient.
6 A. Yeah.
7 Q. The vendor is ZHP, right?
8 A. Just a moment. Yeah, I have
9 read through it.
10 Q. Okay. So the FDA at least
11 at this point expected that Torrent would
12 prove there's no NDMA in the API, right?
13 A. No. Can you repeat your
14 question?
15 Q. At this point, according to
16 Dawn Chitty, the FDA is expecting that
17 Torrent is going to prove there is no
18 NDMA in the API, right?
19 A. Yes.
20 Q. "The statements from the
21 vendor are not sufficient." Meaning
22 those declaration ZHP gave you are not
23 sufficient.
24 MS. BRANCATO: Objection to

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1 form.
2 THE WITNESS: This is said
3 in the mail. This mail has, like
4 it is nothing like that -- there's
5 some communication happen between
6 the FDA and Dawn Chitty. And
7 based upon that fact, she is
8 writing this mail.
9 It is her own assessment.
10 It has nothing to do with FDA,
11 because with FDA, we are giving
12 all the details to them. And
13 based upon that, FDA has only
14 given us a clearance to go back to
15 the market.
16 BY MS. PENDLEY:
17 Q. Okay. You told me at the
18 beginning of this depo the way Torrent
19 communicates with the FDA is through
20 their U.S. representative, right?
21 A. Yeah, it's true.
22 Q. Dawn Chitty, right?
23 A. Correct.
24 Q. Dawn Chitty, your U.S.

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1 representative whose job it is to
2 communicate with the FDA, is saying the
3 FDA is expecting that we prove there's no
4 NDMA in the API, right?
5 A. Yeah, that is the first
6 statement, is very correct. The second
7 writing, I'm not sure, I'm not sure what
8 we need to do. This is now assumption.
9 Q. Okay. Let's look at the
10 next e-mail. It is to directly you, so
11 you can give me your thoughts. It says,
12 "Sushil, Dawn and I will call you
13 tomorrow to discuss this topic. All
14 customers have been backordered and every
15 single day counts as our
16 failure-to-supply penalties will start
17 kicking in."
18 A. Which mail are you referring
19 to?
20 Q. The one above Dawn Chitty.
21 A. Right above the Dawn Chitty.
22 Q. Yep. Just moving towards
23 the top of the page.
24 A. That one has Arunesh mail.

<p>Page 258</p> <p>1 Q. Right. And he sends it to 2 you. 3 A. Mm-hmm. 4 Q. Yes. And so the e-mail 5 says, "Sushil" -- do you see this part? 6 A. Yes. It's Arunesh on that 7 mail. Yeah, sure. 8 Q. They say, "All customers 9 have been back ordered and every single 10 day counts." Right? 11 A. Yeah. 12 Q. It goes on to say, "As our 13 failure-to-supply penalties will start 14 kicking in." 15 A. Yeah. 16 Q. So Torrent is going to have 17 to start paying penalties if it doesn't 18 get their stuff back on the market, 19 right? 20 MS. BRANCATO: Objection. 21 Foundation. 22 THE WITNESS: Maybe. I'm 23 not really sure. But yes, it's 24 been written in the mail.</p> <p>Page 259</p> <p>1 BY MS. PENDLEY: 2 Q. Do you remember this 3 conversation? 4 A. Yeah, I remember this 5 conversation. 6 Q. Okay. So you remember being 7 informed that Torrent was going to have 8 to pay supply penalties if they didn't 9 put valsartan back on the market, right? 10 A. See, this is -- this is the 11 assessment of the market situation they 12 have given. 13 Q. Right. It was given to you, 14 right? 15 A. Yeah, it's true. 16 Q. And you make decisions about 17 whether or not the drug goes back on the 18 market? 19 A. Yeah, but that has no impact 20 on the decisionmaking process. Your 21 decision is always based upon the 22 science. And that -- this isn't -- 23 you're not taking -- that's why I 24 indicated, it is not a one-way</p>	<p>Page 260</p> <p>1 decisionmaking process. We release the 2 batches to the market. 3 The agreed piece of 4 information is being provided to the 5 regulator. And once the regulator is 6 convinced, then only we go to the market. 7 But it has nothing to do with whether the 8 market is dry or whatever the case may 9 be. 10 Q. I mean, you would hope not. 11 You would hope it would be based on the 12 science and not the money. But here we 13 see they want to set up a call with you 14 to discuss the failure-to-supply 15 penalties, right? 16 MS. BRANCATO: Objection to 17 form. 18 THE WITNESS: Yeah, agreed. 19 So and the mail communication, I'm 20 not saying that it is not written. 21 But the decisionmaking 22 process is always based upon 23 science and that is what I 24 indicated. If it is a one-sided</p> <p>Page 261</p> <p>1 decision made without consulting 2 agencies, if some decision being 3 taken, it's different. 4 But here that is what I've 5 indicated, going back to the 6 market call is being taken into 7 consultation with agency, whatever 8 the database they were needing to 9 basically give that call is being 10 provided. And then only we gone 11 back to the market. 12 BY MS. PENDLEY: 13 Q. Do you remember how much 14 these penalties were for? 15 A. Pardon? 16 Q. Do you remember how much the 17 supply penalties were for? 18 A. I'm not sure. 19 Q. Okay. So you're saying that 20 the supply penalties didn't factor into 21 the decision to put the drug back on the 22 market. But if you look at the date, 23 it's July 18, 2018, Torrent put their 24 product back on the market the next day,</p>
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1 right?

2 MS. BRANCATO: Objection to

3 form and foundation.

4 THE WITNESS: No. You're

5 referring to some other mail?

6 BY MS. PENDLEY:

7 Q. Do you remember the day

8 Torrent put their product back on the

9 market?

10 A. I remember on which date FDA

11 has given me clearance to go back on the

12 market.

13 Q. What day was that?

14 A. That date, I think it was --

15 it is on the 18th of July.

16 Q. What's the date of this

17 e-mail?

18 A. No, can you repeat?

19 Q. Yeah. What is the date of

20 this e-mail about supply penalties?

21 A. That is 18th.

22 Q. Mm-hmm. July 18th?

23 A. Yeah.

24 Q. Same day y'all get the drugs

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1 put back on the market?

2 A. Yeah, yeah. But that is

3 independent of this mail.

4 Q. Okay. All right. Let's --

5 MS. PENDLEY: Okay. Let's

6 look at LP 1302.

7 (Document marked for

8 identification as Exhibit

9 Torrent-220.)

10 MS. PENDLEY: This will be

11 Torrent Exhibit 220.

12 THE WITNESS: Yeah.

13 BY MS. PENDLEY:

14 Q. Let me know when you've got

15 it. Do you see the e-mail?

16 A. Yeah.

17 Q. All right. If you will go

18 down to the bottom of the first page.

19 It's from Dawn Chitty. She says, "We've

20 been given permission to release the

21 batches that are quarantined currently."

22 Right?

23 A. Just a moment. Yeah.

24 Q. All right. Let's go up to

Page 264

1 the top e-mail from Dawn Chitty.

2 A. That is 18th of July mail?

3 Q. The 19th. But it's the

4 first e-mail at the top of the page.

5 A. Okay.

6 Q. So Dawn Chitty says, "I've

7 not discussed the testing with them

8 further." She's referencing the FDA if

9 you want to look around. It says, "Right

10 now, they're obviously okay without

11 testing of the C batches." It goes on to

12 say, "Internally, I think it's important

13 to have this information to head off

14 potential liability."

15 Do you see that?

16 A. Yeah. Yeah.

17 Q. Okay. So Dawn Chitty --

18 Dawn Chitty thinks you guys need to

19 figure out the testing method to head off

20 potential liability, right?

21 MS. BRANCATO: Objection to

22 foundation.

23 BY MS. PENDLEY:

24 Q. You can answer.

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1 A. Just -- I'm going through

2 the mail content. Give me just minute.

3 Q. Okay.

4 A. She's raising a very valid

5 aspect here. So this is what she is

6 writing, that we need to continue to put

7 our efforts into reports and developing a

8 method. And we're supposed to be

9 ensuring that we are able to develop a

10 method and test even the D lot, because

11 the D lot is being used for the market.

12 This is what she has written.

13 Q. Right. But you can agree,

14 she doesn't say all that. She says we

15 need this information to head off

16 potential liability, right?

17 A. So frankly speaking, the

18 mail say ultimately, if you look really

19 into the subject of the mail, it is route

20 of synthesis inquiry. It is not

21 called -- this mail is not being written

22 for any commercial purpose. This is for

23 the discussion of the technical aspect.

24 And if we look into the

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1 technical aspect of the mail it says it
2 is all about developing a method and
3 analyzing the batches and the rest. This
4 is what is just a discussion between the
5 group.

6 Q. Okay. I'm just asking what
7 Dawn Chitty says right there. It says,
8 "We have to have this information to head
9 off potential liability," right?

10 A. Yeah, it's written, and I'm
11 not denying. But for me, the aspect of
12 the mail is this.

13 Q. Okay. I'm going to shift
14 gears and do one more thing with you.

15 MS. PENDLEY: If we can pull
16 up LP 1240.

17 (Document marked for
18 identification as Exhibit
19 Torrent-221.)

20 MS. PENDLEY: Which will be
21 Torrent Exhibit 221.

22 And the Bates number is
23 TORRENT-MDL2875-00208351.

24 A. Can I print this? Because

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 on expanding this it can become easy.
2 And can you give me two minutes? So
3 that -- I'm printing it.

4 THE WITNESS: Can you print
5 this immediately?

6 MS. PENDLEY: Yeah, we'll go
7 off the record and let you print
8 it.

9 THE VIDEOGRAPHER: The time
10 now is 11:43 a.m. We're going off
11 the record.

12 (Short break.)

13 THE VIDEOGRAPHER: The time
14 is now 11:47 a.m. We're back on
15 the record.

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

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1 [REDACTED]
2 [REDACTED], great. We've
3 got that.
4 MS. PENDLEY: Let's pull up
5 LP 1218.
6 THE WITNESS: The
7 investigation?
8 (Document marked for
9 identification as Exhibit
10 Torrent-79.)
11 MS. PENDLEY: LP 1218 has
12 been already marked as Torrent-79.
13 To the trial tech, if we
14 could, I would like to kind of
15 keep the chart from 1240 up while
16 we look at 1218, if that's
17 possible.
18 THE WITNESS: The document
19 is loading.
20 MS. PENDLEY: Okay. Hang
21 on. We're waiting on the trial
22 tech.
23 THE WITNESS: Okay.
24 MS. PENDLEY: Okay, great.

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1 BY MS. PENDLEY:
2 Q. So in LP 1218, if we could
3 look at Row 74. Thankfully these rows
4 are numbered. And it's going to be based
5 on the number that's actually typed in
6 the document, not the Excel line. Here
7 we go. Okay. So Row 74, we can see that
8 batch number again, the BV65D002.
9 MS. PENDLEY: We can go back
10 down to Row 74 in 1218. The row
11 74 that's actually typed onto the
12 document, please.
13 MS. BRANCATO: Madeline, is
14 this -- is LP 1218 an exhibit
15 that's been entered.
16 MS. PENDLEY: Yeah.
17 Torrent-79. It's been previously
18 marked.
19 MS. BRANCATO: Got it.
20 Thank you.
21 BY MS. PENDLEY:
22 Q. Okay. So what we're doing,
23 we're looking at the batch number that's
24 listed in LP 1240. We're finding it on

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1 LP 1218, and it's on Row 74. We see that
2 batch again, BV65D002.
3 Do you see that,
4 Mr. Jaiswal?
5 A. Yeah, which is yellow
6 highlighted.
7 Q. Okay. And you see that same
8 number again in the spreadsheet below it?
9 A. No, I'm not able to see that
10 in the spreadsheet. Again, yeah, it is
11 there, but for our purposes here, I'm not
12 able to see that.
13 Q. So that's the same batch
14 that's listed above. If it's small, I
15 apologize. And then it gives us --
16 MS. PENDLEY: I'll let him
17 get situated. Okay. Let's just
18 highlight the whole row, 74.
19 We'll work with that.
20 BY MS. PENDLEY:
21 Q. We see in LP 1218 there's
22 the same batch number that's listed in LP
23 1240, the column that says "NDMA result
24 TPL."

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1 Do you see that?
2 A. 19.8?
3 Q. Yes. So that means this
4 batch has 19.8 parts per million of NDMA
5 in it, right?
6 A. Mm-hmm, yeah.
7 Q. Okay. This document, as you
8 can see in that title line at the top of
9 the spreadsheet, it says "Detailed of
10 finished good batches." So this is 19.8
11 parts per million in the finished dose
12 right?
13 A. The NDMA, the result is API
14 result.
15 Q. This is the API result?
16 A. Yeah.
17 Q. Okay. The document says
18 detailed finished good batches at the
19 top. You're saying this is testing the
20 API?
21 A. I'm not really able to have
22 a look at this data. Just a moment. The
23 74 number row?
24 Q. Yep.

<p>Page 274</p> <p>1 A. Amlo and valsartan 2 10-milligram and 60-milligram tablet, 3 batch number 002. And the API which is 4 being used is the batch number 264. And 5 the manufacturer batch number is 047N, 6 has the impurity, 19.8; is that correct? 7 Q. Yes. That's exactly what 8 I'm looking at. 9 A. Okay. 10 Q. Okay. So 19.8. That's over 11 the FDA threshold of .3 parts per 12 million, right? 13 A. Yeah, yeah. Okay. 14 MS. PENDLEY: Then, let's go 15 to -- we're going to look at LP 16 1240 again. 17 BY MS. PENDLEY: 18 Q. We're just going to go back 19 and forth between these two documents for 20 a minute, okay? 21 Looking at LP 1240, I want 22 to look at batch BV77D013 which happens 23 to be under the one that we just looked 24 at, Row 6.</p> <p>Page 275</p> <p>1 A. Yeah. This is the what you 2 indicated the batch, yeah. 3 Q. Do you see that batch in Row 4 6, BV77D013? 5 A. Yeah. This is different 6 batch number, yeah. 7 Q. We also see that it says, 8 "QC delayed," which is quality control, 9 right? 10 A. Yeah. 11 Q. And then in the next cell, 12 we see, "The sample was received dated on 13 January 24, 2018, and OOS observed in RS 14 test." 15 So OOS is out of 16 specification, right? 17 A. Yeah. 18 Q. And again, RS is residual 19 solvent, right? 20 A. Not necessarily residual 21 solvent. This may be a related 22 substance. 23 Q. So it may be a related 24 substance test, not a residual solvent</p>	<p>Page 276</p> <p>1 test? 2 A. Yeah. 3 Q. Okay. You told me on the 4 other batch it was residual solvents. 5 You think this one is different? 6 A. No. Basically, the -- only 7 it says RS test, so I'm not sure if it is 8 related substance or is it residual 9 solvent. 10 Q. Okay. So we don't know 11 which one it is? 12 A. No. 13 Q. Okay. Then it was released 14 in March, right? 15 A. Just a moment. Sorry. It's 16 actually heavily raining outside, so they 17 are closing the window. 18 Q. Okay. No, you're fine? 19 A. I'm so sorry. It's very 20 heavy rains outside. 21 Q. No, you're okay. All right. 22 One second. So if we look at LP 1218, 23 Row 88 by what's numbered on the 24 document. We once again see that same</p> <p>Page 277</p> <p>1 batch that we just looked at, the 2 BV77D013. 3 Do you see it? 4 A. Yeah. 5 Q. Okay. And once again, it 6 has 19.8 parts per million of NDMA, 7 correct? 8 A. The same lot of API. 9 Q. Right. So that finished 10 good batch is also contaminated, right? 11 A. Yeah. 12 Q. Okay. So we can see that a 13 batch that had been tested in January of 14 2018 ultimately contained NDMA, right? 15 MS. BRANCATO: Objection to 16 form. 17 Go ahead, Sushil. 18 THE WITNESS: This -- the 47 19 batch, it looks like it was going 20 to 03 batches. 21 BY MS. PENDLEY: 22 Q. What do you mean the 47 23 batch, the API batch? 24 A. Yeah.</p>
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1 Q. Okay. Right. So that API
2 batch was used in this batch, and this
3 was tested in January, right?
4 MS. BRANCATO: Objection to
5 form.
6 THE WITNESS: The full data
7 is not --
8 BY MS. PENDLEY:
9 Q. I'm sorry, you broke up.
10 A. -- is refer to -- the sample
11 was received in --
12 (Audio interruption.)
13 MS. BRANCATO: It's probably
14 the storm. Sushil, hang on.
15 Can you start your answer
16 over? I think the storm is
17 interfering with the internet a
18 bit.
19 THE WITNESS: I think, yes,
20 I'm getting an "internet is
21 unstable."
22 MS. BRANCATO: I can hear
23 you now if you want to try again.
24 BY MS. PENDLEY:

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1 Q. What was your answer? I'm
2 sorry.
3 A. I'm just trying to
4 understand the data. So, yes, the 47
5 batch of API is maybe used in more than
6 one batch. This is why I'm trying --
7 Q. Right. No, you're right.
8 It definitely is used for more than one
9 batch. You'll see it couple times on
10 this spreadsheet.
11 A. Okay.
12 Q. Okay. We're seeing the
13 finished dose batch is what got an out of
14 spec observation back in January, right?
15 A. Yeah.
16 MS. BRANCATO: Objection to
17 form.
18 BY MS. PENDLEY:
19 Q. Okay. We'll look at one
20 more from LP 1240. It's Row 10.
21 BV84D010.
22 Same thing, we see that the
23 sample was received in January. Out of
24 trend observed in RS test.

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1 Do you see that?
2 A. Yeah. I'm looking at that
3 but I'm not able to understand what is
4 the conclusion is being drawn out of it.
5 Q. You're not able to
6 understand the conclusion that's being
7 drawn on the out of spec testing? Is
8 that what you're asking?
9 A. Yeah, these are -- these are
10 out-of-specification results. Then there
11 must be further investigation to
12 understand what are the reason or purpose
13 of specification.
14 Q. Right.
15 A. And the two drugs in the
16 same product, the impurity may be because
17 of -- for the amlodipine as well.
18 Q. Right. Okay. We actually
19 tried to find the reason for the out of
20 spec or out of trend result in the
21 production, and we couldn't find one. So
22 this is all we have.
23 A. Yeah, but looking into this,
24 I cannot be able to tell you that,

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1 whether it is OOT or OOS, that it's
2 because of which reason, because there is
3 -- there are two APIs here, the valsartan
4 as well as the amlodipine.
5 And amlodipine is also a
6 very -- like another molecule. So this
7 result may be for any of the API. It is
8 not necessarily it is because of the
9 valsartan or because of the amlodipine.
10 We need to really look into the database.
11 Q. Okay. I understand that.
12 But what we can see right here is this
13 batch did get out of trend in an
14 observation of an RS test, right?
15 A. Yeah, exactly. Because
16 which reason, what is the investigation
17 is not known from this data.
18 Q. Got it. All right. So
19 let's look at LP 1218 one more time. And
20 then Row 101. We see this batch again.
21 And we see that it also, you know, used
22 the same API batch. And it also has
23 19.8 parts per million of NDMA, right?
24 A. Yeah. But until and unless

<p>Page 282</p> <p>1 we don't look into that investigation, I 2 cannot be commenting on that why this OOS 3 and OOT is there, because there are two 4 drug components, amlodipine and 5 valsartan. And until and unless we don't 6 look into the report, we cannot determine 7 why this OOS or OOT data was, so. 8 Q. I got it. We'll talk about 9 that a little more later. 10 Okay. 11 MS. PENDLEY: Can we take a 12 quick break. I think we're going 13 to switch questioners soon. 14 THE VIDEOGRAPHER: The 15 time -- I'm sorry. Go ahead, 16 Counsel. 17 MS. PENDLEY: No, you're 18 good. Just ten minutes. 19 THE VIDEOGRAPHER: The time 20 now is 12:02 p.m. We're going off 21 the record. 22 (Short break.) 23 THE VIDEOGRAPHER: The time 24 is now 12:14 p.m. We're back on</p>	<p>Page 284</p> <p>1 that I want to ask you some questions 2 before the break for the night for you. 3 Okay. I first want to talk 4 about just the technology itself, not the 5 method, just the technology. 6 That GC-MS, that stands for 7 gas chromatography mass spectrometry, 8 right? 9 A. Yeah. 10 Q. And LC-MS, that stands for 11 liquid chromatography mass spectrometry, 12 right? 13 A. Yeah. 14 Q. And GC-MS is technology that 15 has been commonly used since the 1980s, 16 correct? 17 A. Since when it is being used, 18 I'm not really sure, but it is quite old 19 technology. 20 Q. In fact, GC-MS was commonly 21 used in the pharmaceutical industry since 22 the 1980s, correct? 23 A. Since when it is being used, 24 I'm not sure. But yes, it is old</p>
<p>Page 283</p> <p>1 the record. 2 MR. NIGH: Mr. Jaiswal? 3 THE WITNESS: Hi. 4 MR. NIGH: Okay. I don't 5 see him on the video. It didn't 6 pop up. Mr. Jaiswal, can you say 7 something again? 8 THE WITNESS: Are you able 9 to see me on the video? 10 MR. NIGH: There we go. 11 Yeah, absolutely. 12 - - - 13 EXAMINATION 14 - - - 15 BY MR. NIGH: 16 Q. So Mr. Jaiswal let me 17 introduce myself. My name is Daniel 18 Nigh. I represent the plaintiffs in this 19 litigation. Good evening. 20 A. Good evening. 21 Q. We've been going for some 22 time. Here in a little bit we'll break 23 for the night and we'll come back and do 24 some more questioning. But before we do</p>	<p>Page 285</p> <p>1 technology and is being used in the 2 industry since long time. 3 Q. Okay. And LC-MS is 4 technology that has been commonly used 5 since the 1990s, correct? 6 A. Again, I will tell you that 7 for LC-MS also is being old technology, 8 and it is being used very regularly. But 9 from which year, I'm not quite sure. 10 Q. And LC-MS was commonly used 11 in the pharmaceutical industry since the 12 1990s, correct? 13 A. Is being used in the Pharma 14 industry since long time. 15 Q. Okay. 16 A. Which yeah, I'm not sure. 17 Q. As opposed to which year, 18 you know that GC-MS and LC-MS have been 19 used for decades, correct? 20 A. Yeah, that's correct. 21 Q. You understand that 22 scientific literature studies have 23 detected nanograms of NDMA and NDEA and 24 other nitrosamines since the 1980s and</p>

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1 1990s using GC-MS and LC-MS, correct?
2 A. I'm not aware of it.
3 Q. You're not aware of studies
4 that actually detect NDMA and/or NDEA,
5 either in medications or in other
6 applications using GC-MS and LC-MS?
7 A. I'm aware of it, that these
8 technique is being used for analysis of
9 GC-MS and LC-MS. Recently it has been
10 used to analyze NDMA and NDEA. But since
11 how long it is being used, I'm not sure
12 about it.
13 Q. Are you aware that it's been
14 used for decades, that they've been able
15 to detect to the level of nanograms of
16 NDMA and NDEA utilizing GC-MS and LC-MS?
17 A. So again, these techniques I
18 do agree is a decade-old technologies and
19 is being used for different kind of
20 analysis and characterization, but how
21 long it is being used, since how long it
22 has been used for NDEA and NDMA, I'm not
23 really sure.
24 Q. Do you realize that many of

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1 the literature studies that detect NDMA
2 and NDEA utilizing GC-MS and/or LC-MS,
3 that they also describe the method and
4 validation process for detecting NDMA and
5 NDEA in those studies?
6 MS. BRANCATO: Objection to
7 form.
8 THE WITNESS: I've not gone
9 through such kind of database.
10 BY MR. NIGH:
11 Q. Are you aware of any
12 studies? Have you ever taken a look
13 yourself at any of these studies that
14 describe the method and the validation
15 process as to how they were able to
16 detect NDMA and NDEA in nanograms --
17 A. See --
18 Q. -- utilizing --
19 A. No --
20 Q. -- GC-MS and LC-MS?
21 MS. BRANCATO: Sushil, let
22 Daniel finish his question and
23 then you can give your answer.
24 THE WITNESS: Okay. Very

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1 good.
2 So I've seen like as method
3 which is being published by FDA
4 using these techniques.
5 Definitely I have found through
6 those methods.
7 BY MR. NIGH:
8 Q. You're aware of the FDA
9 having published these techniques decades
10 ago?
11 MS. BRANCATO: Objection to
12 form.
13 THE WITNESS: These -- they
14 have published methods post on
15 this discovery. And they have
16 published several methods,
17 recently, in 2018-'19 and I've
18 seen --
19 BY MR. NIGH:
20 Q. I see. I'm actually -- I
21 think you're speaking about after there
22 was a discovery of NDEA and/or NDMA in
23 valsartan, then the FDA started to
24 publish these techniques. So I'm

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1 speaking before that, just the technology
2 and method, that there were actually
3 methods described in scientific
4 literature studies that show how they
5 detected and quantified NDMA and NDEA
6 utilizing gas chromatography and liquid
7 chromatography.
8 Are you aware of that?
9 A. No, I'm not aware of it.
10 But the gas chromatography is different
11 from the gas chromatography mass
12 spectroscopy, because it is a --
13 different altogether.
14 Q. Yeah, let me be real clear.
15 I understand your answer to say gas
16 chromatography is different from gas
17 chromatography mass spectrometry. I'm
18 speaking solely to gas chromatography
19 mass spectrometry, the coupling of the
20 two, okay, that has been around for
21 decades, gas chromatography mass
22 spectrometry.
23 A. I've not seen it. I have
24 not gone through such literature.

<p>Page 290</p> <p>1 Q. Okay. You haven't seen the 2 literature where they describe methods as 3 to how they use gas chromatography mass 4 spectrometry, and/or liquid chromatography 5 mass spectrometry to be able to identify 6 and quantify to the level of nanograms 7 the amount of NDMA and NDEA that they are 8 seeking to research? You haven't seen 9 that?</p> <p>10 A. For NDEA and NDMA, I have 11 not seen it.</p> <p>12 Q. So you wouldn't be able to 13 speak then, if you haven't reviewed those 14 studies, you wouldn't be able to speak as 15 to how long those methods have been 16 around for, correct?</p> <p>17 A. See, these techniques is 18 being used for some other purposes. So 19 this is not the only use of the 20 technology. This technology is being 21 used for several other purpose also 22 within the pharma industry, and that's 23 why I'm indicating that these techniques 24 being used since long time in pharma</p> <p>Page 291</p> <p>1 industry.</p> <p>2 Q. Are you aware of the 3 potential for medicines to nitrosate, or 4 nitrosation? Have you ever heard of 5 that?</p> <p>6 A. This is chemistry. So 7 basically I'm a quality person. So 8 really I need to really check this with 9 my chemistry people, who is really 10 supporting the chemistry.</p> <p>11 Q. Are you aware that back in 12 the 1970s and 1980s they had concerns 13 that with drugs like cimetidine and 14 ranitidine, that they had the potential 15 to nitrosate, meaning they could break 16 down into NDMA, NDEA, or other 17 nitrosamines inside of the body?</p> <p>18 MS. BRANCATO: Objection to 19 form.</p> <p>20 BY MR. NIGH:</p> <p>21 Q. In the 1970s and 1980s?</p> <p>22 A. No, I have not seen it.</p> <p>23 Q. You wouldn't be aware of the 24 scientific literature studies and/or</p>	<p>Page 292</p> <p>1 studies carried out by those 2 pharmaceutical industries where they were 3 actually utilizing GC-MS and LC-MS to 4 detect how much NDMA, NDEA, and other 5 nitrosamines were breaking down inside 6 the body as a result of use of the drug?</p> <p>7 A. This what you are talking 8 about is basically a clinical portion of 9 the, like, science, pharmaceutical 10 science. You talk about the blood plasma 11 analysis. And this is all about a very 12 different field altogether.</p> <p>13 So you're talking about the 14 plasma analysis and identifying those 15 levels in the plasma. And you're talking 16 about those studies. Yeah, basically I'm 17 not sure.</p> <p>18 Q. And are you also aware that 19 they would also -- they would also be 20 able to test the amount of NDMA and/or 21 NDEA inside of the drug itself back in 22 the 1980s using gas chromatography mass 23 spectrometry?</p> <p>24 A. I have not seen it.</p> <p>Page 293</p> <p>1 Q. Okay. So when 2 pharmaceutical companies want to use new 3 testing methods, they will commonly apply 4 to the FDA to be able to use these 5 testing methods for day-to-day 6 activities, correct?</p> <p>7 A. So if I'm understanding your 8 question correctly, you're indicating 9 that method which is being developed for 10 day-to-day analysis using this technique?</p> <p>11 Q. The question is when 12 pharmaceutical companies want to use new 13 testing methods, they will commonly apply 14 to the FDA to be able to use these 15 testing methods for day-to-day 16 activities, correct?</p> <p>17 A. So I think no, I'm not very 18 in agreement, because whenever I'm 19 devising an a new test method, if it is a 20 new product, then basically there's a new 21 ANDA submission.</p> <p>22 But if is existing product, 23 then it has to go through that 24 verification application.</p>
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<p>Page 294</p> <p>1 Q. The verification application 2 is precisely what I'm asking here. So 3 let me ask the question again using that 4 wording. 5 Pharmaceutical companies -- 6 when pharmaceutical companies want to use 7 new testing methods, they will commonly 8 apply utilizing a verification 9 application to the FDA to be able to use 10 these testing methods for day-to-day 11 activities, correct? 12 MS. BRANCATO: Objection to 13 form and foundation. 14 THE WITNESS: No. I think 15 I'm still not in very great 16 agreement with this statement. 17 See, like, the method is 18 being devised and designed based 19 upon your set of requirement and 20 once it is being designed and 21 devised, that method is to be, if 22 it is a non-pharmacopeia, it is to 23 be validated and submitted to the 24 agency as a part of your ANDA</p> <p>Page 295</p> <p>1 supplement. 2 BY MR. NIGH: 3 Q. Torrent could have made an 4 application to the FDA to use one of the 5 many methods discussed in scientific 6 literature for detection of NDMA and 7 NDEA, correct? 8 MS. BRANCATO: Objection to 9 form and foundation. 10 THE WITNESS: Can you repeat 11 your question? 12 BY MR. NIGH: 13 Q. Torrent could have made an 14 application to the FDA to use one of the 15 many methods discussed in scientific 16 literature for the detection of NDMA and 17 NDEA, correct? 18 MS. BRANCATO: Same 19 objections. 20 THE WITNESS: I'm not sure 21 about it. 22 BY MR. NIGH: 23 Q. Prior to August of 2018, 24 Torrent never made an application to the</p>	<p>Page 296</p> <p>1 FDA to use any of the methods discussed 2 in scientific literature for the 3 detection of NDMA and NDEA, correct? 4 MS. BRANCATO: Objection. 5 Foundation. 6 BY MR. NIGH: 7 Q. You can answer. 8 Mr. Jaiswal? 9 A. Yeah. 10 Q. You can answer that 11 question. 12 A. Yeah, you're indicating 13 whether we proposed to FDA for 14 utilization of this technique for 15 analysis of NDEA and NDMA before 2018? 16 Q. No, I'm asking you a 17 question. Prior to August of 2018, 18 Torrent never made an application to the 19 FDA to use any of the methods discussed 20 in scientific literature for the 21 detection of NDMA and NDEA, correct? 22 MS. BRANCATO: Same 23 objection. 24 THE WITNESS: No, but</p> <p>Page 297</p> <p>1 this -- I'm not able to 2 understand, because why I need to 3 make application if ANDA has not 4 required that in those supplements 5 or those changes? 6 BY MR. NIGH: 7 Q. We'll talk about that later. 8 But my question is, prior to August 2018, 9 Torrent never made an application to the 10 FDA to use any of the methods discussed 11 in scientific literature for the 12 detection of NDMA and NDEA, correct? 13 MS. BRANCATO: Same 14 objection. 15 THE WITNESS: Again, I'm 16 indicating because my 17 specifications are not naming 18 these impurities and that -- no 19 need to approach FDA for this 20 purpose. 21 (Audio interference.) 22 THE COURT REPORTER: The 23 audio cut out on that answer. 24 BY MR. NIGH:</p>
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<p style="text-align: right;">Page 298</p> <p>1 Q. Mr. Jaiswal, could you give 2 that answer again. I think you cut out 3 in the middle of your answer. 4 THE WITNESS: Hello. 5 MS. BRANCATO: Sushil? 6 THE WITNESS: Yes. 7 MS. BRANCATO: Can you hear 8 us? 9 THE WITNESS: Yes. 10 MS. BRANCATO: Okay. Can 11 you give that last answer again? 12 THE WITNESS: Which last 13 answer? 14 BY MR. NIGH: 15 Q. Let me ask the question 16 again. You cut out in the middle of your 17 answer the last time. 18 So I said we'll talk about 19 the -- you had mentioned why you would 20 need to do that, make an application if 21 ANDA -- it's not required in those 22 supplements or changes, talking about why 23 you do the testing. 24 My question is -- we'll talk</p>	<p style="text-align: right;">Page 300</p> <p>1 you change -- or amend your specification 2 or you change your -- 3 (Audio interference.) 4 (Whereupon, a discussion was 5 held off the stenographic record.) 6 THE WITNESS: The internet 7 is not working very strong because 8 there is very heavy rains outside. 9 This started and that 10 sometimes, there is some 11 disturbance in the internet and 12 quality of the internet. 13 BY MR. NIGH: 14 Q. Okay. Let me pick up where 15 we were, because you had said that based 16 upon lifecycle -- based upon lifecycle 17 assessment and management, if you have a 18 situation where you need to change your 19 either specification or amend or 20 change -- and that's kind of where the 21 audio blipped. 22 So can you pick up on that 23 answer or restate that answer from the 24 beginning?</p>
<p style="text-align: right;">Page 299</p> <p>1 about that later. But my question is, 2 prior to August of 2018, Torrent never 3 made an application to the FDA to use any 4 of the methods discussed in scientific 5 literature for the detection of NDMA and 6 NDEA, correct? 7 A. Yeah, in my product, this 8 NDMA and NDEA was not part of the 9 specification. And that's why it was not 10 needed to approach the FDA. 11 Q. So is it your testimony that 12 if it's not included in the ANDA, then 13 there is never a scenario where you would 14 need to make an application to the FDA to 15 amend an ANDA? 16 MS. BRANCATO: Objection to 17 form. 18 BY MR. NIGH: 19 Q. You can answer. 20 A. So once you have approved 21 ANDA in place, and based upon your 22 lifecycle assessment and management, if 23 you have a situation where you need to 24 change your -- either your specification,</p>	<p style="text-align: right;">Page 301</p> <p>1 A. For that, if you 2 supported -- if that needed an addition 3 of new method, test method, then 4 basically you design that method, develop 5 that method, validate it, and then submit 6 this to agency as a supplement. And that 7 supplement may be for any category that 8 meets the requirement. 9 Q. The lifecycle assessment and 10 management, that's -- you have to 11 continue to follow your drug throughout 12 the lifecycle of the drug, correct? 13 MS. BRANCATO: Objection to 14 form and foundation. Outside the 15 scope. 16 You can answer in your 17 personal capacity. 18 BY MR. NIGH: 19 Q. Mr. Jaiswal, you can answer. 20 A. Yeah, this aspect is 21 basically handled by the 22 pharmacovigilance group. And if you -- 23 if you are asking me more detail about 24 it, I may not be able to answer it.</p>

<p style="text-align: right;">Page 302</p> <p>1 Q. I simply asked, because you 2 answered it in your answer, where you 3 said based upon your lifecycle assessment 4 and management. That's why I asked the 5 question. 6 So in your answer, you 7 stated based upon your lifecycle 8 assessment and management, if you have a 9 situation where you need to change -- do 10 you recall giving that answer, that part 11 of the answer? 12 A. Yeah, that is correct, but 13 then -- 14 Q. I -- sorry. Go ahead. 15 A. If it is that situation, 16 then basically you are developing a 17 method and validating and you are 18 submitting it to agency. 19 Q. So in order to understand 20 your answer on the "based upon your 21 lifecycle assessment and management," or 22 to understand your words that you just 23 gave to me, I'm asking you, lifecycle 24 assessment and management, that means</p>	<p style="text-align: right;">Page 304</p> <p>1 are, did you ever make an application to 2 the FDA for new testing methods, and your 3 answer comes back, well, we did it 4 according to the specifications in the 5 ANDA. 6 It's not been my question. 7 But now I'm going to go with you. Okay. 8 And my question is going to be, yes, I 9 understand that you have ANDA 10 requirements. Okay. But when you become 11 aware of some safety implication and/or 12 some potential changes, you, as Torrent, 13 have the power and authority to file an 14 amended ANDA application that allows or 15 gives you the ability to use these new 16 testing methods that I'm speaking about, 17 correct? 18 MS. BRANCATO: Objection. 19 Outside the scope of the 30(b)(6). 20 You can answer. 21 THE WITNESS: Can I answer? 22 MS. BRANCATO: Yep. 23 BY MR. NIGH: 24 Q. Yes.</p>
<p style="text-align: right;">Page 303</p> <p>1 that you have to continue to follow your 2 drug even after you get initial approval, 3 correct? 4 MS. BRANCATO: Objection to 5 form. 6 THE WITNESS: What I've 7 explained, the supplement filing 8 is always postapproval. Once -- 9 I'm indicating that the supplement 10 if is to be filed that applies to 11 the situation, a postapproval 12 changes. 13 BY MR. NIGH: 14 Q. If you become aware of 15 certain circumstances or issues or there 16 are some changes or any safety issues 17 that are implicated during the lifecycle 18 assessment and management of the product, 19 you can make updates or applications to 20 the FDA to amend the ANDAs, correct? 21 A. I think I'm not very clear 22 on this topic. 23 Q. Well, you keep answering -- 24 your answers in response to my question</p>	<p style="text-align: right;">Page 305</p> <p>1 A. See, once you talk about the 2 safety, the safety is a very different 3 aspect altogether. And once I'm talking 4 about the testing method that comes into 5 the quality. The safety is basically a 6 very different aspect altogether. Once 7 you bring a safety aspect into the 8 discussion, you become a different field 9 altogether. 10 That is basically a -- that 11 is a kind of a safety and medical team 12 handles it. So this is what I indicated. 13 It becomes a very different area of 14 discussion altogether. 15 Q. When you become aware of 16 some quality implication, and/or some 17 potential changes, you as Torrent have 18 the power and authority to file an 19 amended ANDA application that allows you 20 to give you the ability to use these new 21 testing methods to assess the quality of 22 that product, correct? 23 MS. BRANCATO: Objection to 24 foundation. Outside the scope.</p>

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1 You can answer.
2 BY MR. NIGH:
3 Q. Mr. Jaiswal, when your
4 attorney makes an objection, you can
5 still answer. Okay?
6 A. Okay. If your specification
7 and analytical methods needs any kind of
8 amendment, yes, we do a validation and we
9 do file a supplement to the agency.
10 Q. Okay. In addition
11 pharmaceutical companies can use new
12 testing methods even without specific FDA
13 approval for that specific testing
14 method, as long as they are also using
15 the approved testing methods already
16 approved by the FDA in the ANDA as well,
17 correct?
18 MS. BRANCATO: Objection to
19 form.
20 THE WITNESS: So I'm not in
21 agreement. Whenever we use the
22 method for any of the testing, it
23 is always an approved method. And
24 whenever we are developing a new

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1 method, basically we file a
2 supplement and we get this
3 approved by the agency.
4 BY MR. NIGH:
5 Q. You're aware that before
6 approval of an ANDA and/or DMF, Torrent
7 could have used any of the methods
8 discussed in the scientific literature
9 for the detection of NDMA and/or NDEA,
10 correct?
11 MS. BRANCATO: Objection to
12 form. Foundation. And outside
13 the scope.
14 THE WITNESS: I'm not really
15 sure about this testing method.
16 BY MR. NIGH:
17 Q. I heard you talk about the
18 synthetic chemistry analysis on multiple
19 occasions with Ms. Pendley.
20 Do you remember that?
21 A. Synthetic chemistry?
22 Q. Yes. Do you know what
23 synthetic chemistry means?
24 A. Yeah, I know. But it is not

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1 my area, synthetic chemistry is
2 definitely a different department we have
3 who is taking care of the synthetic
4 chemistry.
5 MR. NIGH: Let's pull up LP
6 1527, your resumé.
7 This was previously marked
8 as Exhibit 215, used earlier
9 today.
10 BY MR. NIGH:
11 Q. Mr. Jaiswal, this is your
12 resumé. I'm going to turn your attention
13 to Page 3 of your resumé, professional
14 qualifications.
15 A. I'm just trying to open it.
16 Q. Okay.
17 A. Torrent -- which number?
18 Q. Page 3. Page 3. Do you see
19 that there?
20 MS. BRANCATO: He's asking
21 the exhibit number.
22 BY MR. NIGH:
23 Q. The exhibit number -- the
24 exhibit number is 215. It's also up on

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1 the screen here, your resume.
2 A. 215.
3 Q. 215 yes. 215.
4 A. 215.
5 Q. Let's look at your
6 qualifications, professional
7 qualifications. It appears that you've
8 got a master's in science degree in 1992.
9 Do you see that?
10 A. Yeah.
11 Q. And that was for applied
12 chemistry, correct?
13 A. Correct.
14 Q. And then in 2021 -- that's
15 this year, right?
16 A. Yeah.
17 Q. You got your Ph.D.?
18 A. Yes.
19 Q. Congrats.
20 A. Thank you.
21 Q. And so do you go by
22 Dr. Jaiswal or Mr. Jaiswal?
23 A. Now, it is Dr. Jaiswal, but
24 I allow to be called as Mr. Jaiswal only.

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1 Q. Oh, you only want to be
2 called Mr. Jaiswal?
3 A. Yeah, I'm really okay with
4 that.
5 Q. Okay. All right. Okay.
6 Well, here you got your Ph.D. It was for
7 chemistry, method development and
8 validation.
9 Do you see that?
10 A. Yes.
11 Q. What does that mean?
12 A. Basically this involves an
13 analytical method development for some of
14 the molecules and those method is being
15 developed, validated and is being taken
16 for the publication.
17 Q. Okay. And you had mentioned
18 that you had published articles as part
19 of your Ph.D. Do you remember that,
20 journal scientific articles?
21 A. Yes.
22 Q. When did you publish those
23 articles?
24 A. I suppose it is somewhere in

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1 that -- between 2015, 2017.
2 Q. Between 2015 and 2017?
3 A. Yes.
4 Q. I want to see if I've got
5 this right. So while you were the head
6 of quality at Torrent, you held a
7 master's in science, but you didn't have
8 a Ph.D. at that time yet, right?
9 A. Yes. When I joined this
10 organization, I was a master of science.
11 Q. Okay. Now, what does --
12 chemical synthesis, what does that mean?
13 A. So because I'm not basically
14 a chemical person, so I'm not able to
15 give that definition to you.
16 But chemical synthesis is
17 once you are -- like there are several
18 reactions. And based upon those
19 reactions, if you synthesize something,
20 it would be a synthetic chemistry.
21 Q. Okay. Let me see if I have
22 this right. When you're doing a chemical
23 synthetic analysis, you are looking at
24 your starting material with the ultimate

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1 goal of what your ending byproduct --
2 your ending product is going to be,
3 correct?
4 MS. BRANCATO: Objection to
5 form and foundation.
6 THE WITNESS: I think I'm
7 not able to really understood your
8 question.
9 BY MR. NIGH:
10 Q. I'm sorry. You said that
11 you weren't able to understand my
12 question?
13 A. Yeah.
14 Q. When you're doing -- do you
15 know -- have you heard of a chemical
16 synthetic analysis?
17 A. Chemical synthetic analysis?
18 No.
19 Q. Have you -- earlier you
20 responded to Madeline, Ms. Pendley, that
21 when you do the chemistry -- do you
22 remember saying, when you do the
23 chemistry?
24 MS. BRANCATO: Objection to

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1 form.
2 THE WITNESS: You are
3 referring to what topic? Because
4 what I had indicated that I think
5 what I'm referring to by
6 identification of the impurity, a
7 chemical, like how the API is
8 being synthesized, that ROS is to
9 be reviewed, and then it needs to
10 be basically identified, whatever
11 the process impurity, whatever the
12 degradation impurity. That was
13 the discussion topic.
14 BY MR. NIGH:
15 Q. Okay. So when you're doing
16 the chemistry, that's another way of when
17 you're doing the synthetic chemistry
18 analysis or synthetic chemical analysis,
19 where you're trying to look at your
20 starting product, what your ultimate goal
21 for end product is, and then all of the
22 potential byproducts, correct?
23 A. Yeah, but this is what I
24 explained, but this is always being done

<p>Page 314</p> <p>1 by the chemistry team who is basically 2 synthesizing a product, and they always 3 have a -- like, they are the expert on 4 those topic. 5 Q. Right. But the chemistry 6 team at Torrent never came to you as the 7 head of quality and said, "Hey, we can 8 see when we look at the chemical 9 synthetic process as to how our valsartan 10 is being made that there's the potential 11 for NDMA and NDEA being formed"? Right, 12 your chemistry teacher -- your chemistry 13 team never informed you of that, correct? 14 A. So I will tell you that as 15 a -- like whenever we receive an open 16 part of the DMF, it is always being 17 reviewed by the chemistry team. Now the 18 information which is being given within 19 the open part of DMF is always limited. 20 And with the knowledge or 21 with the information which is being 22 given, it is not always possible to 23 really identify the level of impurities 24 indicated in the API.</p> <p>Page 315</p> <p>1 And that is why this 2 assessment is to be done by the DMF 3 holder, because they only know what is 4 the whole chemistry scheme, what are the 5 process parameter, and how it is being 6 synthesized. 7 Q. That was a very long answer. 8 But I'm going to go ahead and try to 9 tweak this as we discuss. 10 When looking at synthetic 11 chemical analysis to understand what 12 impurities or contaminants could make its 13 way into the drugs, it's important to 14 fully understand the ingredients that are 15 being used in the drug, correct? 16 A. No. I think, say, why -- 17 you know that what are the ingredient, 18 the alone ingredient, the key starting 19 material, is not the only way to identify 20 the impurity. 21 What you need, you need the 22 reagent, solvents, residual conditions, 23 the special -- which has being given by 24 the test so manufacturing process, you</p>	<p>Page 316</p> <p>1 are supposed to know the KSM. You're 2 supposed to know how KSM is being 3 synthesized, what are the impurities 4 coming into the KSM, and how it is being 5 mitigated into the process. 6 All these information is 7 always with the DMF holder. It's never 8 being with the ANDA holder. 9 Q. I appreciate that you gave 10 me a lot of the factors that go into a 11 chemical synthetic analysis. I 12 understand that you have a lot of 13 information on this now. 14 What I'm asking is, just 15 simply the one part that, as one part of 16 a complete synthetic chemical analysis, 17 it's important to understand what 18 impurities or contaminants could make its 19 way into the ingredients that you're 20 using in making the drug, correct? 21 A. So to understand, like, 22 impurity profile generated out of any 23 chemical scheme, this is what I think 24 your question is.</p> <p>Page 317</p> <p>1 And I'm again emphasizing 2 that to do that job, you need the 3 complete chemistry involved. That means 4 the incoming -- your key starting 5 material, your KSM, your solvents, the 6 catalyst, the temperature, the pressure. 7 And above that there's a lot 8 of testing being done while developing an 9 API. There are a lot of process studies 10 being done. What kind of order design of 11 the process is to get rid of those 12 impurity that is being identified. 13 So these -- all database is 14 always and always being restricted in the 15 restricted part of the DMF and is never 16 being with the ANDA holder. 17 And with that -- with that, 18 I wanted to tell you that those 19 information, my chemistry team is looking 20 into, they may not be able to identify 21 the potential on those synthesis. 22 Q. We're going to talk about 23 the always being restricted to the DMF in 24 a minute. Okay. But I want to come back</p>
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1 to some other parts of this question
2 first.
3 The synthetic -- a complete
4 synthetic chemical analysis is only as
5 good as the variables it considers,
6 correct?
7 MS. BRANCATO: Objection to
8 form.
9 THE WITNESS: No. Not quite
10 sure about that.
11 BY MR. NIGH:
12 Q. Meaning if variables are
13 missed in the synthetic chemical
14 analysis, then the analysis may miss
15 impurities or contaminants that could be
16 formed, correct?
17 A. No, I think I'm not able to
18 answer this based upon this limited
19 portion. I think I need a little bit
20 more elaboration in the question to
21 answer it correctly.
22 Q. If you don't understand that
23 there are impurities or contaminants in
24 the ingredients themselves, then the

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1 synthetic chemical analysis will also
2 possibly miss these impurities or
3 contaminants, correct?
4 A. This, you're talking for the
5 API synthesis?
6 Q. I'm talking about just a
7 general synthetic chemical analysis.
8 Chemical synthesis 101.
9 If you don't understand that
10 there are impurities or contaminants in
11 the ingredients themselves, then the
12 synthetic chemical analysis will also
13 miss these impurities or contaminants,
14 correct?
15 A. No, I think I'm not able to
16 answer that, because I think this is to
17 be purely answered by some person who is
18 handling the chemistry day in, day out.
19 Q. Well, you're designated for
20 the topics that we have you designated
21 for on 30(b)(6). I think it will speak
22 for itself.
23 Had Torrent understood that
24 the recycled solvents containing NDMA and

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1 NDEA -- I'm sorry. Strike that.
2 Had Torrent understood that
3 the valsartan API that they were getting
4 from ZHP contained NDMA and NDEA, then
5 they would have also understood in their
6 synthetic chemical analysis that the
7 valsartan API made -- or the valsartan
8 that Torrent is making in terms of
9 finished product made with valsartan ZHP
10 API would also have potentially NDMA and
11 NDEA, correct?
12 MS. BRANCATO: Objection to
13 form.
14 BY MR. NIGH:
15 Q. You can answer. Anytime
16 your attorney objects, she hasn't the
17 instructed you not to answer.
18 A. No, I'm really trying to
19 analyze your question, because it is too
20 much away from quality. I'm really
21 trying to analyze it, to -- how to answer
22 your question. So like --
23 Q. Let me simplify it.
24 Had Torrent understood that

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1 the valsartan ZHP API that they were
2 getting contained NDMA and NDEA, then
3 they would have also been able to
4 understand in their synthetic chemical
5 analysis on Torrent making the finished
6 product that the finished product would
7 be capable of having NDMA and NDEA,
8 correct?
9 A. As I said, my specification
10 for the finished product and for the
11 API --
12 MR. NIGH: Take a look at LP
13 1516. This will be marked as
14 Exhibit 222.
15 (Document marked for
16 identification as Exhibit
17 Torrent-222.)
18 BY MR. NIGH:
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 A. Getting downloaded.

2 Q. I'm sorry. Did you say it's
3 getting downloaded?

4 A. Yeah, it's getting
5 downloaded. Because of poor internet
6 quality, it is taking time.

7 Q. Okay. Do you have it now?

8 A. No, I think it's taking too
9 much.

10 MR. NIGH: Let's go off the
11 record.

12 THE VIDEOGRAPHER: The time
13 is now 12:56 p.m. We're going off
14 the record.

15 (Brief pause.)

16 THE VIDEOGRAPHER: The time
17 is now 1 o'clock p.m. We are back
18 on the record.

19 BY MR. NIGH:

20 Q. Okay. This document is
21 marked as Torrent Exhibit 222.

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[REDACTED]

[REDACTED]

<p>Page 326</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 330</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 334</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 338</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

<p>Page 342</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

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[REDACTED]

13 Q. Okay. Mr. Jaiswal, I
14 believe it's almost midnight your time.
15 Would now be a good time for you to take
16 a break for the day?

17 A. I'm okay, fine.

18 Q. You'd like to take a break
19 for the day?

20 A. That's fine. Thank you.

21 MR. NIGH: Okay. Let's go
22 ahead and take a break for the day
23 and we'll resume in the morning.
24 Okay.

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[REDACTED]

1 THE WITNESS: Thank you.
2 Thank you, everyone.

3 MR. NIGH: Thank you, sir.

4 THE VIDEOGRAPHER: The time
5 now is 1:26 p.m. This concludes
6 today's deposition. We're going
7 off the record.

8 (Excused.)

9 (Adjourned approximately
10 1:26 p.m. eastern standard time.
11 (11:06 p.m. India standard time.)

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CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, SUSHIL JAISWAL, Ph.D., have the opportunity to read and sign the deposition transcript.

MICHELLE L. GRAY,
A Registered Professional
Reporter, Certified Shorthand
Reporter, Certified Realtime
Reporter and Notary Public
Dated: June 8, 2021

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 354, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

SUSHIL JAISWAL, Ph.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

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Exhibit 97

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE
4 -----|
5 |
6 IN RE: VALSARTAN, LOSARTAN, | Hon. Robert B. Kugler
7 AND IRBESARTAN PRODUCTS |
8 LIABILITY LITIGATION | Civ. No. 19-2875 (RBK)
9 |
10 This Document Relates to: |
11 All Actions. |
12 |
13 -----|

14 CONFIDENTIAL INFORMATION - SUBJECT TO
15 PROTECTIVE ORDER
16 Monday, September 27, 2021

17 - - -
18 This is the Remote Videotaped Deposition of
19 Humana Pharmacy, Inc.'s Corporate Representative,
20 CESAR CEDENO, pursuant to Fed. R. Civ. P. 30(b)(6),
21 commencing at 9:02 a.m., on the above date, before
22 Susan D. Wasilewski, Registered Professional
23 Reporter, Certified Realtime Reporter, Certified
24 Manager of Reporting Services, Certified Realtime
25 Captioner, and Florida Professional Reporter.

26 - - -
27 GOLKOW LITIGATION SERVICES
28 877.370.3377 ph | 917.591.5672 fax
29 deps@golkow.com
30

Page 2	Page 4
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Page 3	Page 5
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<p style="text-align: right;">Page 6</p> <p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 HUMANA PHARMACY, INC., DEPOSITION EXHIBITS PAGE</p> <p>4 Exhibit 8 Anda Purchase History for Humana 59</p> <p>Pharmacy, Inc., Between Jan 1, 2013</p> <p>5 and Dec 31, 2019</p> <p>HUM000150 through 163</p> <p>6</p> <p>Exhibit 9 Transaction History Log 68</p> <p>7 Date Range: 2012-01-01 to</p> <p>2020-08-11</p> <p>8 HUM000990</p> <p>9 Exhibit 10 NDC Package Code and Purchase Order 69</p> <p>Documents</p> <p>10 HUM000164 through 283</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 testimony you're about to give will be the truth,</p> <p>2 the whole truth, and nothing but the truth?</p> <p>3 THE WITNESS: I do.</p> <p>4 THE COURT REPORTER: Thank you.</p> <p>5 CESAR CEDENO, called as a witness by the</p> <p>6 Plaintiffs, having been first duly sworn, testified</p> <p>7 as follows:</p> <p>8 DIRECT EXAMINATION</p> <p>9 BY MS. GOLDENBERG:</p> <p>10 Q. All right. Good morning, Mr. Ceden. We</p> <p>11 met briefly off the record but, again, my name is</p> <p>12 Marlene Goldenberg and I'm going to be taking your</p> <p>13 deposition today. All right?</p> <p>14 A. Good morning.</p> <p>15 Q. And before we get started, I notice there's</p> <p>16 a little delay in your sound. I'm wondering if you</p> <p>17 can move your computer a little bit closer so that</p> <p>18 the court reporter has an easier time hearing you.</p> <p>19 A. I'm using the microphone in the room, so</p> <p>20 I'll try to move that closer to me.</p> <p>21 Q. All right. And if the court reporter has a</p> <p>22 problem, I assume she'll tell us, but your voice is</p> <p>23 a little soft, so I just want to make sure we all</p> <p>24 can hear you this morning.</p> <p>25 So why don't we start with the basics. Can</p>
<p style="text-align: right;">Page 7</p> <p>1 - - -</p> <p>2 THE VIDEOGRAPHER: We're now on the record.</p> <p>3 My name is Judy Diaz. I'm a legal videographer</p> <p>4 for Golkow Litigation Services. Today's date is</p> <p>5 September 27th, 2021, and the time is 9:02 a.m.</p> <p>6 This remote video deposition is being held</p> <p>7 in the matter of Valsartan, Losartan, and</p> <p>8 Irbesartan Products Liability Litigation MDL.</p> <p>9 The deponent is the Cesar Ceden.</p> <p>10 All parties to this deposition are appearing</p> <p>11 remotely and have agreed to the witness being</p> <p>12 sworn in remotely. Due to the nature of remote</p> <p>13 reporting, please pause briefly before speaking</p> <p>14 to ensure all parties are heard completely.</p> <p>15 Will counsel please identify themselves.</p> <p>16 MS. GOLDENBERG: This is Marlene Goldenberg</p> <p>17 on behalf of the Plaintiffs and the PSC.</p> <p>18 MS. IVES: And Kirstin Ives, I-v-e-s, on</p> <p>19 behalf of Humana Pharmacy, Inc., and Mr. Ceden.</p> <p>20 THE VIDEOGRAPHER: The court reporter is</p> <p>21 Susan Wasilewski and will now swear in the</p> <p>22 witness.</p> <p>23 THE COURT REPORTER: Would you raise your</p> <p>24 right hand?</p> <p>25 Do you solemnly swear or affirm the</p>	<p style="text-align: right;">Page 9</p> <p>1 you state your full name for the record, please?</p> <p>2 A. Yes. Cesar Ceden.</p> <p>3 Q. All right. And you are here to testify</p> <p>4 today on behalf of Humana. You understand that?</p> <p>5 A. I do.</p> <p>6 Q. And you also understand that your testimony</p> <p>7 is binding on the company?</p> <p>8 A. I do.</p> <p>9 MS. GOLDENBERG: All right. So why don't we</p> <p>10 bring up the deposition notice, which is Number</p> <p>11 39, please; and we'll mark this as Humana</p> <p>12 Exhibit 1. It should be Number 39.</p> <p>13 MS. MATTSSEN: I'm sorry. For some reason,</p> <p>14 it only goes up to 29.</p> <p>15 MS. GOLDENBERG: Let's go off for one</p> <p>16 second.</p> <p>17 MS. MATTSSEN: Okay. Sorry. Okay.</p> <p>18 THE VIDEOGRAPHER: The time right now is</p> <p>19 9:06 a.m. We're off the record.</p> <p>20 (Recess from 9:06 a.m. until 9:11 a.m.)</p> <p>21 THE VIDEOGRAPHER: The time right now is</p> <p>22 9:11 a.m. We're back on the record.</p> <p>23 MS. GOLDENBERG: All right. I appreciate</p> <p>24 your indulgence in our fixing some technical</p> <p>25 issues. We're back on the record, and we're now</p>

<p style="text-align: right;">Page 10</p> <p>1 going to pull up Tab 39, and this will be the 2 deposition notice, and this will be Humana 3 Exhibit 1. 4 (Humana - Cedeno Exhibit 1 was marked for 5 identification.) 6 BY MS. GOLDENBERG: 7 Q. Mr. Cedeno, as we've discussed, you are here 8 today to discuss certain topics and -- or to testify 9 on behalf of certain topics on behalf of Humana as 10 they relate to the brick-and-mortar pharmacy 11 locations; is that correct? 12 A. That's correct. 13 Q. All right. And my understanding from your 14 counsel is that specifically, that includes 15 Topics -- 16 MS. GOLDENBERG: If we could scroll down to 17 where the topics are listed. 18 Q. That includes Topics 3, 4, 6, 7, 9, 10, and 19 12 as they relate to the brick-and-mortar locations. 20 That's correct? 21 A. Read the numbers again. 3, 6, you said? 22 Q. 3, 4, 6, 7, 9, 10, and 12. Your counsel is 23 mouthing, if that helps. 24 A. Yeah, that's correct. That's correct. 25 Thank you.</p>	<p style="text-align: right;">Page 12</p> <p>1 number of different forms. There was valsartan on 2 its own. There was valsartan plus amlodipine, 3 valsartan plus hydrochlorothiazide, or HCTZ, but the 4 main ingredient we care about for this case is 5 valsartan. 6 You understand that? 7 A. Yes, I do. 8 Q. In other words, we're not here to talk about 9 any issues with amlodipine or HCTZ, correct? 10 A. Correct. 11 Q. Okay. So I'm going to ask you questions 12 today about valsartan, and when I use that term, I 13 need to apply it to all three different formulations 14 of valsartan that was sold by Humana. 15 Is that fair? 16 A. Yes. 17 Q. Okay. That will save us all a lot of air. 18 If you feel like there's a need to distinguish 19 between the forms, I'm going to rely on you to tell 20 me that, but, otherwise, I'm going to assume that 21 your answers apply to all three. 22 Is that reasonable? 23 A. Yes. 24 Q. Okay. So you understand that the reason 25 that we're here today is because Humana sold</p>
<p style="text-align: right;">Page 11</p> <p>1 Q. Okay. That's the only time I'm going to let 2 her answer a question for you. 3 MS. GOLDENBERG: But I appreciate your help 4 on that one. 5 Q. Okay. And so my understanding is that 6 Humana has -- today at least, has roughly 35, 36 7 brick-and-mortar locations; is that correct? 8 A. I believe it's 45. 9 Q. 45. See, I counted wrong last night. Okay. 10 And those 45 locations are scattered around the 11 country, right? 12 A. Correct. 13 Q. All right. And what percentage of Humana's 14 business or of its pharmacy business is comprised by 15 those 45 brick-and-mortar locations? 16 A. I do not know that. I know that we are 17 called a rounding error, so I don't think it's a 18 lot. 19 Q. Okay. I think that says everything we need 20 to know. And so suffice it to say, this as very 21 small percentage of Humana's business, correct? 22 A. (No audible response.) 23 Q. Okay. So let's just talk about some basic 24 terminology that we're going to use today. We 25 understand that valsartan actually was sold in a</p>	<p style="text-align: right;">Page 13</p> <p>1 valsartan medications that were contaminated with 2 unsafe levels of nitrosamines; is that correct? 3 MR. Reefer: Object to form. 4 MS. IVES: Object to form. 5 You can go ahead and answer. 6 THE WITNESS: Oh, okay. 7 A. Ask the question again. Sorry. 8 Q. You understand that the reason we're here 9 today is to talk about valsartan medications that 10 Humana sold that contained unsafe levels of 11 nitrosamines, right? 12 MR. HERROLD: Object to form, foundation. 13 MR. REEFER: Object to form. 14 THE WITNESS: (Garbled audio.) 15 MS. IVES: Unless I instruct you not to 16 answer -- 17 THE WITNESS: Got it. 18 MS. IVES: -- you can answer -- 19 THE WITNESS: Okay. 20 MS. IVES: -- once everyone is done 21 objecting. 22 A. Yes, I understand. 23 Q. Okay. And I should note there might be some 24 objections to my questions today. As your attorney 25 just indicated, unless someone instructs you not to</p>

<p>Page 14</p> <p>1 answer the question, you can go ahead -- wait for 2 them to make the objection, and then move forward 3 with your answer. The attorneys will deal with the 4 objections at another time when you don't have to 5 sit through it. All right? 6 A. (No audible response.) 7 Q. And I didn't hear your answer come through 8 on that. 9 A. I said yes. 10 Q. Okay. 11 (Discussion off the record.) 12 MS. GOLDENBERG: Is there a way that we can 13 have one attorney making the objections on behalf 14 of everyone? 15 MR. REEFER: I think that's fine, Marlene. 16 The problem is -- this is Jason Reefer on behalf 17 of Mylan Pharmaceuticals. The problem is I don't 18 necessarily know if anybody else is going to 19 voice the objection that I intend to voice, so 20 I'm not sure there's an easy solution without us 21 all being in the same room like the old days. 22 MS. GOLDENBERG: Didn't bring your -- you 23 didn't bring your mind-reading devices with you 24 today? All right. Well, let -- 25 MR. REEFER: No, ma'am.</p> <p>Page 15</p> <p>1 MS. GOLDENBERG: Let's do this. If we can 2 all do our best to have one attorney object; 3 otherwise, if you want to object, maybe for the 4 court reporter's sake, you can be on camera. 5 MR. REEFER: Oh, I don't think that will 6 benefit anybody but, okay, I understand. 7 MS. GOLDENBERG: Well, I'll leave it up to 8 the court reporter. 9 THE COURT REPORTER: If I don't catch who 10 says it, I'm just going to call it "Defense 11 Counsel," if that's okay. 12 MR. REEFER: That's fine with me if it's 13 fine with Marlene. I think -- if I'm not 14 mistaken, I think there's some rule in one of the 15 PTOs that an objection to one is objection to 16 all, so... 17 MS. GOLDENBERG: I believe that is what the 18 pretrial order says, so as long as it's on behalf 19 of everyone, that's fine. 20 MR. REEFER: Okay. Thank you. 21 THE COURT REPORTER: Thank you. I 22 appreciate that. 23 MS. GOLDENBERG: All right. Are we good to 24 go forward? I take that as a yes. 25 BY MS. GOLDENBERG:</p>	<p>Page 16</p> <p>1 Q. All right. Mr. Cedeno, do you have an 2 understanding that NDMA and NDEA belong to a class 3 of n-nitroso compounds called nitrosamines? 4 A. Yes, I understand that. 5 Q. And what is your general understanding of 6 what a nitrosamine is? 7 MS. IVES: Objection; outside -- 8 MR. REEFER: Object to -- 9 MS. IVES: -- the scope. 10 You can answer to the extent you know. 11 A. The only thing I know is that it's been 12 grouped in with potentially hazardous effects, 13 cancer-causing agents. 14 Q. Cancer-causing agents, you said? 15 A. Yes, that's what I said. 16 Q. All right. Suffice it to say no patient 17 wants to buy a drug with cancer-causing agents in 18 it, right? 19 A. I -- well, I would not think anyone would 20 like it, yeah, correct. 21 Q. All right. When was the first time that 22 Humana found out that its medication -- or that its 23 valsartan medications contained nitrosamines? 24 MS. IVES: Objection; form and foundation. 25 A. I don't have any documents in front of me,</p> <p>Page 17</p> <p>1 but if you'd like to refresh my memory, that would 2 be fine. 3 Q. This isn't something that you prepared to 4 answer today? 5 A. Not a specific date. 6 Q. All right. How did Humana find out that 7 its -- some of its valsartan medications were 8 contaminated with nitrosamines? 9 A. Well, I'll speak of normal course of 10 business. When there is a recall or anything that 11 requires us to pay attention to something like this, 12 it would be sent to us from the retail pharmacy part 13 of Humana, it would be sent to us from our 14 professional practice, which I believe Nathan 15 Hunnell can probably give a little bit more detail 16 as to how their process works. 17 My understanding is that they get 18 information from the FDA and/or our distributors 19 when something is recalled. 20 Q. Do you have any specific knowledge about 21 whether Humana found out from a publically available 22 FDA recall notice or whether they were contacted by 23 a distributor or a manufacturer of the drug first? 24 A. In this case, I have no idea which one came 25 first.</p>
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<p style="text-align: right;">Page 18</p> <p>1 Q. Who would be the point person at Humana who 2 would generally get that information? 3 A. So normally our professional practice group. 4 Nathan Hunnell with Humana is one of the pharmacists 5 that are in our professional practice group. They 6 receive that information, disseminate it out to the 7 different groups that potentially have impacted 8 patients. Current state, someone else, but back 9 then, it would have been Nathan Hunnell. 10 Q. All right. And Humana is also aware that 11 not all of the valsartan available in the United 12 States was recalled for nitrosamine contamination, 13 right? 14 MS. ANDRAS: This is Tiffany Andras for 15 Teva, and I just want to lodge an objection to 16 the use of the word "contaminant" -- 17 "contamination," a continuing objection to any 18 question that characterizes it that way on the 19 basis of foundation. 20 MS. GOLDENBERG: And obviously we disagree, 21 but sure. 22 A. I don't -- I don't recall every single one, 23 but I'm pretty confident that it's -- it was not 24 every single manufacturer of valsartan -- 25 Q. Does Humana continue --</p>	<p style="text-align: right;">Page 20</p> <p>1 BY MS. GOLDENBERG: 2 Q. So, Mr. Cedeno. What I have in front of you 3 is a multipage document. It is a printout of the 4 FDA's sartan recall update list that appears on its 5 website. 6 Have you seen this document before? 7 A. Probably. It looks very familiar. 8 Q. All right. This is something that Humana 9 would be monitoring in the regular course of its 10 business? 11 A. I would assume so. Again, that's 12 professional practice, not a -- not something I 13 would do on a normal course of business. 14 Q. All right. It would be important for 15 someone at Humana to be monitoring this, though, to 16 make sure that the medications Humana was selling 17 were safe, right? 18 A. Absolutely. We definitely don't want to 19 dispense anything that's unsafe. 20 Q. Right. Okay. So why don't we -- 21 MS. GOLDENBERG: Leah, if you can run a 22 Control F for the word "interim" and get down to 23 the part where they actually talk about the 24 levels. There we go. So if you can -- we need 25 to get to the part with the table. All right.</p>
<p style="text-align: right;">Page 19</p> <p>1 A. -- (garbled audio) -- 2 Q. I'm sorry. Did Humana -- does Humana 3 continue to sell valsartan in the United States 4 today? 5 A. I don't -- I don't know of all of Humana's 6 business, but in retail pharmacy, I don't believe we 7 are dispensing any at this moment. 8 Q. You're not dispensing any valsartan today? 9 A. Not to my knowledge. 10 Q. Okay. You're aware, though, that it is 11 possible to manufacture valsartan without NDMA in 12 it, correct? 13 MR. REEFER: Object to form, foundation. 14 MS. IVES: Objection; outside the scope of 15 the designated topics. 16 You can answer if you know of your personal 17 knowledge. 18 MR. REEFER: Object to form and foundation. 19 A. I can assume. I don't know. I don't -- I 20 don't work in manufacturing, so I don't know. 21 Q. All right. 22 MS. GOLDENBERG: Why don't we pull up Tab 23 40, please, which will be Humana Exhibit 2. 24 (Humana - Cedeno Exhibit 2 was marked for 25 identification.)</p>	<p style="text-align: right;">Page 21</p> <p>1 So it should be Page 8. There we go. 2 Q. Are you aware that the FDA has imposed 3 interim acceptable limits for various levels of 4 nitrosamines in valsartan? 5 MR. REEFER: Object to form and foundation. 6 MS. IVES: Objection, it's, again, outside 7 the scope of what he's been called to testify on 8 on behalf of Humana. 9 If you would know in your personal capacity, 10 you can answer. 11 A. I do not know. 12 Q. Okay. Do you have an understanding that the 13 reason that a number of medications were recalled 14 was because the levels in the pills exceeded these 15 interim thresholds right in front of you for 16 different levels of nitrosamines? 17 MR. REEFER: Object to form and foundation. 18 A. Yeah, I can see on the graph in front of me 19 that there's an acceptable intake of NDMA's on this 20 chart. 21 Q. And Humana understands that the reason that 22 various valsartan medications were recalled was 23 because the levels exceeded the levels that you have 24 in front of you, right? 25 MR. REEFER: Same objection.</p>

<p style="text-align: right;">Page 22</p> <p>1 A. Yes, that was the reason for the recall.</p> <p>2 MS. GOLDENBERG: All right. We can take</p> <p>3 that one down.</p> <p>4 Q. Does Humana also understand that the</p> <p>5 valsartan recall resulted from a variety of quality</p> <p>6 issues that the manufacturers had on their end?</p> <p>7 MS. IVES: Objection; form.</p> <p>8 MR. REEFER: Object; foundation.</p> <p>9 A. Again, to my knowledge, it's the amount of</p> <p>10 NDMA in the formations that -- in the formulation</p> <p>11 that caused the recall. I don't -- I don't know</p> <p>12 specifically about the manufacturing practices.</p> <p>13 Q. All right. We can put that exhibit back up</p> <p>14 if you want, but Humana presumably would have read</p> <p>15 all of those FDA press releases about the basis for</p> <p>16 the recall, correct?</p> <p>17 A. Yes, correct.</p> <p>18 Q. All right. And those public press releases</p> <p>19 that were put out by the various manufacturers, in</p> <p>20 conjunction with the FDA, explain that the NDMA</p> <p>21 contamination resulted either from synthesis</p> <p>22 problems in the active pharmaceutical ingredient or,</p> <p>23 in other cases, the use of recovered solvents. Does</p> <p>24 Humana understand that?</p> <p>25 A. Yes. If that's what was in the press</p>	<p style="text-align: right;">Page 24</p> <p>1 which contains the official definition of</p> <p>2 adulterated drugs and devices.</p> <p>3 Do you see that?</p> <p>4 A. I do.</p> <p>5 Q. And this is a statute that Humana would want</p> <p>6 to make sure it was familiar with, right?</p> <p>7 MS. IVES: Objection; outside the scope of</p> <p>8 what he's here to testify about today.</p> <p>9 You can answer to the extent you know.</p> <p>10 A. The profession of pharmacy follows this,</p> <p>11 yes, so I assume that Humana would follow it, too,</p> <p>12 as well. I'm pretty confident that we do follow all</p> <p>13 the -- all the rules and regulations.</p> <p>14 Q. All right. Now, if we look at the beginning</p> <p>15 of Section 351, it says: A drug or device shall be</p> <p>16 deemed to be adulterated...</p> <p>17 And then it gives a bunch of different</p> <p>18 subsections after that. Do you see that?</p> <p>19 A. I do.</p> <p>20 Q. All right. And so if we look at Subsection</p> <p>21 (b) --</p> <p>22 MS. GOLDENBERG: And maybe we can blow that</p> <p>23 up because it looks pretty small to me, if we</p> <p>24 could just zoom in on that part.</p> <p>25 Q. All right. So you'll see that the very</p>
<p style="text-align: right;">Page 23</p> <p>1 release, yes, it's understood.</p> <p>2 Q. All right. And Humana also understands that</p> <p>3 those are quality issues at the manufacturer's</p> <p>4 level, right?</p> <p>5 MS. IVES: Objection to form.</p> <p>6 A. Yeah, if it comes from the manufacturer,</p> <p>7 that is something that the manufacturer would have</p> <p>8 to, I guess, work through, right? It essentially</p> <p>9 would be a quality issue.</p> <p>10 Q. Right.</p> <p>11 MS. GOLDENBERG: All right. Let's put up</p> <p>12 Tab 41. This will be Exhibit 3.</p> <p>13 (Humana - Cedenex Exhibit 3 was marked for</p> <p>14 identification.)</p> <p>15 BY MS. GOLDENBERG:</p> <p>16 Q. And while we're doing that, you've heard the</p> <p>17 term "adulteration," correct?</p> <p>18 A. Yes.</p> <p>19 Q. All right. What is your understanding of</p> <p>20 what that means?</p> <p>21 A. So essentially, it's something that was, I</p> <p>22 guess, altered in a way, changed in a way that it</p> <p>23 wasn't intended to be.</p> <p>24 Q. All right. And so if we look at what you</p> <p>25 have in front of you, this is 21 U.S.C. Section 351</p>	<p style="text-align: right;">Page 25</p> <p>1 beginning of the sentence under Subsection (b) says:</p> <p>2 If it purports to be or is represented as a drug the</p> <p>3 name of which is recognized in an official</p> <p>4 compendium and its strength differs from or its</p> <p>5 quality or purity falls below the standard set forth</p> <p>6 in such compendium.</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. And as we just discussed, the valsartan</p> <p>10 recalls were a subject of a quality issue, correct?</p> <p>11 MS. IVES: Objection; form.</p> <p>12 A. We did say that.</p> <p>13 Q. All right. And if a drug isn't meeting</p> <p>14 quality standards, then under this definition, it</p> <p>15 would be an adulterated drug, right?</p> <p>16 MR. REEFER: Object to the form, foundation,</p> <p>17 calls for a legal conclusion.</p> <p>18 MS. IVES: Objection to form, foundation.</p> <p>19 A. Based on this definition, yes.</p> <p>20 Q. All right. And a -- if a drug is</p> <p>21 adulterated, it's not something Humana would want to</p> <p>22 be selling, which is why they recalled the</p> <p>23 valsartan, right?</p> <p>24 MR. REEFER: Object to form, foundation.</p> <p>25 MS. IVES: Objection to form. Objection to</p>

<p style="text-align: right;">Page 26</p> <p>1 form.</p> <p>2 A. We do not want to be dispensing anything</p> <p>3 that's adulterated, that's correct.</p> <p>4 MS. GOLDENBERG: All right. So we can take</p> <p>5 that one down.</p> <p>6 Q. And you're aware as well that some of the</p> <p>7 manufacturers recalled all of the valsartan that</p> <p>8 they made in the United States, and that includes</p> <p>9 manufacturers like Zhejiang Huahai Pharmaceuticals,</p> <p>10 right?</p> <p>11 MR. HERROLD: Object to the form.</p> <p>12 A. I do -- I do know that our professional</p> <p>13 practice had sent updates to which ones were</p> <p>14 recalled. So as the recall kind of expanded, we</p> <p>15 received more and more information about the</p> <p>16 manufacturers.</p> <p>17 I don't know about all manufacturers. I</p> <p>18 know that the ones that we have purchased were the</p> <p>19 ones that we were given. So I don't know the</p> <p>20 full -- full -- I guess the full scope of all the</p> <p>21 recalls.</p> <p>22 Q. Okay. And we can come back to that later?</p> <p>23 MS. GOLDENBERG: Why don't we put up Tab 43.</p> <p>24 This will be Exhibit 4.</p> <p>25 (Humana - Cedeno Exhibit 4 was marked for</p>	<p style="text-align: right;">Page 28</p> <p>1 reasons that Humana recalled its valsartan is</p> <p>2 because they can't sell drugs that are adulterated,</p> <p>3 like valsartan that's contaminated with NDMA, right?</p> <p>4 MR. REEFER: Objection to form, foundation.</p> <p>5 MS. IVES: Objection. Objection to form.</p> <p>6 A. Yes. Our recall pulls everything we did --</p> <p>7 or informed the retail pharmacies of the reasons for</p> <p>8 the recall, and we immediately stopped selling those</p> <p>9 products.</p> <p>10 Q. Right. Because you couldn't sell a product</p> <p>11 that had unsafe levels of nitrosamines, right?</p> <p>12 MR. REEFER: Object to form, foundation.</p> <p>13 A. In this situation -- in this recall, yes.</p> <p>14 Q. Right. Because to do so would actually be</p> <p>15 unlawful under US law, right?</p> <p>16 MR. REEFER: Same objection.</p> <p>17 MS. IVES: Objection; form, foundation,</p> <p>18 outside the scope of this witness's designated</p> <p>19 topics.</p> <p>20 You can answer to the extent you have</p> <p>21 personal knowledge.</p> <p>22 A. My personal knowledge would say that's my</p> <p>23 understanding.</p> <p>24 Q. All right. And if something can't be sold,</p> <p>25 then it's really not worth anything, right?</p>
<p style="text-align: right;">Page 27</p> <p>1 identification.)</p> <p>2 BY MS. GOLDENBERG:</p> <p>3 Q. And what you can see here on the right-hand</p> <p>4 side, this is 21 U.S.C. Section 331, titled</p> <p>5 Prohibited acts.</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. Thankfully, we don't have to get too far</p> <p>9 into this section, but at the very beginning it</p> <p>10 says: The following acts and causing thereof are</p> <p>11 prohibited.</p> <p>12 And under Section (a) it says: The</p> <p>13 introduction or delivery for introduction into</p> <p>14 interstate commerce any food, drug, or device -- or</p> <p>15 device, tobacco product, or cosmetic that is</p> <p>16 adulterated or misbranded.</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. If we put that in plain English, it's</p> <p>20 unlawful to sell a drug that is adulterated,</p> <p>21 correct?</p> <p>22 MR. REEFER: Calls for a legal conclusion.</p> <p>23 MS. IVES: Objection, form and foundation.</p> <p>24 A. That's my interpretation.</p> <p>25 Q. All right. And so, again, one of the</p>	<p style="text-align: right;">Page 29</p> <p>1 MR. REEFER: Object to form, foundation.</p> <p>2 MS. IVES: Object to form, foundation, and</p> <p>3 outside the cope.</p> <p>4 You can answer in your personal capacity.</p> <p>5 A. I don't understand the question.</p> <p>6 Q. Sure. Not the best question, so let's break</p> <p>7 it down a little bit.</p> <p>8 Humana's a business, right?</p> <p>9 A. Correct. Okay.</p> <p>10 Q. And as a business, Humana is there to sell</p> <p>11 products that will make the business money, right?</p> <p>12 A. Well, we are a for-profit business, so, yes,</p> <p>13 I'm following --</p> <p>14 Q. Right.</p> <p>15 A. -- you so far.</p> <p>16 Q. All right. And so if Humana is in</p> <p>17 possession of some valsartan pills that are</p> <p>18 contaminated with NDMA that can't be sold, they're</p> <p>19 not worth anything because they can't be sold for</p> <p>20 any money -- any money, right?</p> <p>21 MS. IVES: Objection; form, foundation, and</p> <p>22 outside the scope of the designated topics.</p> <p>23 You can answer to your personal knowledge.</p> <p>24 A. Very tricky answer. I guess I'll do the</p> <p>25 best I can personally.</p>

Page 30

1 So we don't make a lot of money selling
2 pharmaceuticals. We make -- it's better for us to
3 take care of a patient as a whole. So long-term,
4 keeping patient's blood pressure, in this case, down
5 is better for the plan than it is selling a
6 prescription.
7 So yes and no I guess you could say is the
8 answer to your question. It's not -- even selling
9 the product is not worth anything to us on the
10 pharmacy side, period, but long-term, it's better
11 for the plan if a patient is on a medication that is
12 potentially life-lengthening, lifesaving.
13 So in this case, it would not be beneficial
14 for Humana to dispense a product that is recalled
15 because that goes against what they're trying to do
16 in keeping a patient healthy.
17 Does that make sense?
18 Q. It does. So there's a -- there's the
19 holistic approach, but what I'm asking about right
20 now is just the monetary value of that single pill
21 that might be sold, and even if it's not going to
22 make Humana millions of dollars on one pill, each
23 pill has a monetary value assigned to it, right?
24 A. That would --
25 Q. For every pill that Humana would sell,

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1 whatever that monetary value is, is what they would
2 make off of the pill, right?
3 A. Sometimes you lose money, but, yes.
4 Q. But that pill isn't worth anything if it's
5 contaminated with nitrosamines, right?
6 MS. IVES: Objection; form, foundation,
7 outside the scope.
8 A. So it would not benefit Humana or the
9 patient to dispense that pill.
10 Q. Right. Because you can't, right? We just
11 talked about that. It's illegal?
12 A. We wouldn't, right.
13 MR. REEFER: Calls for a legal conclusion.
14 Q. Right. And so something you can't sell
15 isn't worth anything, right?
16 MR. REEFER: Same objection.
17 MS. ANDRAS: Objection. Tiffany Andras.
18 Asked, answered. You've asked the question three
19 different, four different times, Marlene.
20 A. It wouldn't be worth anything, if that's
21 what you're asking.
22 Q. Okay.
23 A. Yeah.
24 Q. Thanks.
25 MS. GOLDENBERG: We can take this one down.

Page 32

1 Q. Over the years Humana purchased valsartan
2 from a number of different suppliers; is that right?
3 A. Humana Retail Pharmacies?
4 Q. Yes.
5 A. To my knowledge, we only get it from
6 Amerisource in retail pharmacy.
7 Q. Okay. All right. I'll tell you in the
8 documents -- the contracts that I've seen with the
9 sellers of the pills don't distinguish between the
10 retail pharmacy and the rest of Humana, but if your
11 testimony is that the retail pharmacy only got the
12 drug from AmerisourceBergen, we can focus on that
13 for today. Is that accurate?
14 A. That's accurate to the best of my knowledge,
15 yes.
16 Q. Okay. When was the first time that Humana
17 Retail Pharmacy began purchasing valsartan from
18 AmerisourceBergen?
19 A. I have no idea.
20 MS. GOLDENBERG: All right. Well, why don't
21 we pull up Exhibit 2, and we'll see if this will
22 help get us through this part. I'm sorry. This
23 is Tab 2. It will be Exhibit 5.
24 (Humana - Cedenex Exhibit 5 was marked for
25 identification.)

Page 33

1 BY MS. GOLDENBERG:
2 Q. All right. So what you have in front of you
3 is --
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 When you have looked at purchasing

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1 agreements previously, do they typically mention all
2 the medications that are being purchased?
3 A. I have never looked at a purchasing
4 agreement for pharmaceuticals ever in my career.
5 Q. All right. That's not something that you
6 looked at to prepare for today?
7 A. I potentially flipped through, but it's not
8 part of my normal business or ever has been. I kind
9 of probably just breezed through it, to be honest.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 35

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 And we'll stop there. What is product
9 pedigree?
10 A. To my understanding, since I don't do
11 purchasing -- and this is something that's probably
12 going to go way back to my previous roles in
13 different organizations, a pedigree is basically --
14 shows you that it comes from a manufacturer to a
15 supplier to the pharmacy, so essentially a chain of
16 custody of -- certification, if you will, and that's
17 just to the best of my knowledge. Again, I don't --
18 I don't work with purchasing or supplying, so that's
19 a definition I was told. It may be hearsay. I
20 don't know.
21 Q. All right. Well, I'll leave the objections
22 to your counsel, but -- all right.
23 So to the best of your understanding,
24 pedigree refers to chain of custody; is that right?
25 A. That's the best of my knowledge, yes.

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1 MS. GOLDENBERG: Okay. Why don't we go down
2 to Page 19, please.
3 MS. IVES: And, Ms. Goldenberg, just to --
4 just to be clear, Dan Brais is going to be the
5 one that's more familiar with these purchasing
6 questions. So if you have specific questions, if
7 Mr. Cedenno doesn't know, since he hasn't seen
8 this, he would be the best person to ask
9 tomorrow.
10 MS. GOLDENBERG: Okay. If you're telling me
11 he's going to be able to answer the questions, we
12 will skip over this exhibit.
13 MS. IVES: Yes, exactly. So Mr. Cedenno can
14 talk about the fact that the stores order the
15 drugs, but the actual purchasing and purchasing
16 agreements would fall under Dan's testimony
17 tomorrow.
18 MS. GOLDENBERG: Got it. That's helpful.
19 Thank you.
20 All right. So why don't we take this one
21 down and -- let's see.
22 Q. Mr. Cedenno, are you prepared today to talk
23 about the information that Humana pharmacy tracked
24 when it purchased drugs?
25 A. What do you mean, tracked? Tracked what?

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1 Q. That's fair. It wasn't totally a clear
2 question. Let's start this section and see how we
3 do, and you tell me if this is you or it should be
4 somebody else.
5 When Humana purchases drugs from
6 AmerisourceBergen, tell me, is it provided with, for
7 example, the NDC code affiliated with each of those
8 drugs?
9 A. When we purchase medications from
10 AmerisourceBergen, we do see the NDC code, yes.
11 Q. All right. And when you say you see it, in
12 what way is that information provided to you, and in
13 what way is it kept by Humana?
14 A. So it is -- so once we -- our ordering
15 comes -- starts from our retail locations directly
16 into the Amerisource order website. On that
17 website, we are given information about NDC.
18 Once we purchase that item, and it comes to
19 us, we have invoices with NDCs on it. Once we
20 dispense a product, our system keeps track of the
21 NDC that's being dispensed to the patient.
22 Q. All right. So let's just back up a little
23 bit. You said the pharmacies each place their own
24 orders through the Amerisource portal?
25 A. That's correct.

<p style="text-align: right;">Page 38</p> <p>1 Q. All right. Are those orders tracked at all 2 on the Humana side in a centrally located database? 3 A. Not to my knowledge. 4 Q. Okay. Are those orders tracked by a 5 centrally located Humana billing department 6 anywhere? 7 A. I don't know about that, either. I know 8 that all the records are for in stores. The stores 9 keep their own records of what they purchase. 10 Q. Okay. And so each individual store would be 11 responsible for maintaining purchase records, 12 invoices, et cetera, from AmerisourceBergen; is that 13 right? 14 A. Correct. 15 Q. Okay. So we've covered the NDC code. That 16 information is kept, right? 17 A. NDC code? And the -- yes, it's kept in the 18 stores -- 19 Q. What about -- what about the lot or batch 20 number of valsartan, is that something that's 21 tracked? 22 A. That's not tracked. 23 Q. Okay. So let's say that Amerisource -- that 24 AmerisourceBergen sold Humana Retail Pharmacy seven 25 batches of valsartan, for example. Would those</p>	<p style="text-align: right;">Page 40</p> <p>1 like Aurobindo, right? 2 A. Once it's been dispensed to the patient, 3 that's correct. Once it's -- while it's still in 4 the pharmacy, it is in its manufacturer bottle, so 5 then it can be determined, but again, once it's 6 dispensed to the patient, then no, we would not be 7 able to distinguish. 8 Q. And so the safest thing for Humana to do at 9 that point would be to assume that all of the 10 dispensed medication was contaminated for recall 11 purposes, right? 12 MR. REEFER: Object to form; foundation. 13 A. When we do -- when we have a recall, and we 14 do not have information on lot, batch, or expiration 15 date, we operate under the assumption that all is 16 affected, and we contact all those patients. 17 Q. And the reason that you have to operate on 18 that assumption is because there's no way to 19 guarantee which pills are safe and which ones are 20 not, right? 21 MR. REEFER: Object to form; foundation. 22 A. Again, we operate under the assumption that 23 potentially every single dispense of that particular 24 NDC is potentially affected by the recall. So we 25 would -- we would contact all those patients because</p>
<p style="text-align: right;">Page 39</p> <p>1 individual batches be segregated at Humana's 2 premises, or are they all combined into a single 3 bin? 4 A. It could all be combined in the -- on the 5 shelf together and not in a bin, but in the shelf 6 together. 7 Q. So in other words, does Humana have the 8 ability to determine what lot or batch of valsartan 9 any individual pill on its shelves came from? 10 A. Outside of looking at the manufacturer 11 bottle, not at this time. 12 Q. Okay. And so we discussed this earlier, 13 that there were some manufacturers that recalled all 14 of their valsartan. Are you also aware that there 15 are some manufacturers that only recalled some of 16 its valsartan, like Aurobindo, for example? 17 A. Yes. I'm aware that some -- that the lots 18 were expanded into certain manufacturers all lots 19 and all batches, and some were just certain select 20 ones, yes. 21 Q. If Humana did not have the ability to 22 distinguish between lot and batch numbers for the 23 pills that were in its possession, Humana also 24 wouldn't be in a position to determine which pills 25 were and were not contaminated from a manufacturer</p>	<p style="text-align: right;">Page 41</p> <p>1 there is no way to determine if it is or not. 2 Q. All right. So we've talked about lot and 3 batch number. I assume that expiration date is 4 something that is tracked, correct? 5 A. So the original manufacturer expiration date 6 is not tracked, either. 7 Q. How are expiration dates tracked on Humana 8 medications, or how are they set, I guess? 9 A. So let me go back and explain that a little 10 further, maybe to give some context. 11 So if the manufacturer's bottle indicates 12 that the expiration date is less than one year from 13 the date that we are dispensing that product, at 14 that point, we update the label to indicate the 15 actual expiration date. 16 If the expiration date of the manufacturer's 17 bottle is greater than one year, then our system 18 automatically gives it a one-year expiration date 19 from the date of dispense. So if it was dispensed 20 today, and the expiration date of the product was in 21 2025, it would say 9/27/2022 as the expiration date 22 even though we have essentially until 2025. 23 Does that make sense. 24 Q. It does. Why is that the policy? 25 A. It's a standard practice across all the</p>

<p>Page 42</p> <p>1 different pharmacies I've ever worked for ever, is</p> <p>2 they always give a one-year expiration date on</p> <p>3 dispensed product.</p> <p>4 Q. Okay. Does Humana track the manufacture</p> <p>5 date of the valsartan pills?</p> <p>6 A. Not to my knowledge.</p> <p>7 Q. Okay. Does it track the name of the</p> <p>8 manufacturer?</p> <p>9 A. I'm sorry. You said the name?</p> <p>10 Q. Yes.</p> <p>11 A. We track the NDC, and the NDC would point</p> <p>12 back to the manufacturer's name, but I don't think</p> <p>13 we have a -- potentially, I guess, they could bounce</p> <p>14 information off by using NDC and manufacturer name</p> <p>15 associated with NDC, but I don't know -- you know</p> <p>16 what? Let me take that back.</p> <p>17 So once we dispense a product, our labels do</p> <p>18 indicate that it was -- which NDC it is, and I</p> <p>19 believe it shows the name of the manufacturer, too,</p> <p>20 as well. So somewhere -- somewhere in some report</p> <p>21 I'm sure there is an -- associated with the NDC</p> <p>22 going back to the name.</p> <p>23 Q. Okay. At any rate --</p> <p>24 A. Yeah.</p> <p>25 Q. That's a fair point. At any rate, Humana</p>	<p>Page 44</p> <p>1 they order in large, you know, 1000-count bottles,</p> <p>2 too, 500-count bottles, you know, as well. So yes</p> <p>3 to both. Yes to all, all of the above.</p> <p>4 Q. All right. So it would be fair to say that</p> <p>5 for anything that came in the package that was</p> <p>6 dispensed exactly as it came to the consumer, those</p> <p>7 batches would be -- you could track the manufacturer</p> <p>8 of those bottles, right?</p> <p>9 A. We could track the manufacturers of all the</p> <p>10 bottles by NDC.</p> <p>11 Q. Right. Okay. Fair enough. And you can</p> <p>12 track all of them packaged either way by</p> <p>13 manufacturer or NDC code because the NDC code traces</p> <p>14 back to the manufacturer, right?</p> <p>15 A. NDC code tracks back to the manufacturer,</p> <p>16 correct.</p> <p>17 MS. GOLDENBERG: Okay. Why don't we pull up</p> <p>18 Tab 37, please, and this will be Exhibit 6.</p> <p>19 (Humana - Cedeno Exhibit 6 was marked for</p> <p>20 identification.)</p> <p>21 BY MS. GOLDENBERG:</p> <p>22 Q. All right. So what you have in front of</p> <p>23 you, if we scroll down to the bottom of this first</p> <p>24 page -- sorry, is there a Bates number on this one</p> <p>25 that shows up? There we go. This is HUM001416,</p>
<p>Page 43</p> <p>1 would have the ability to pull that data to</p> <p>2 determine which valsartan pills at least correlated</p> <p>3 to which NDC or to which manufacturer; is that fair?</p> <p>4 A. That's fair. That's correct.</p> <p>5 Q. All right. When Humana purchases drugs --</p> <p>6 let's make it specific. When Humana purchases</p> <p>7 valsartan from AmerisourceBergen, did those pills</p> <p>8 come in bulk packs, or were they prebottled?</p> <p>9 A. They come in the -- in the manufacturer</p> <p>10 bottle. Maybe if you describe to me what's -- what</p> <p>11 do you mean by the two different -- because, to me,</p> <p>12 it's the same thing, what you -- what you asked me.</p> <p>13 The two options mean the same thing to me. I don't</p> <p>14 know. Maybe I'm --</p> <p>15 Q. That's all right. It wasn't a very good</p> <p>16 question. Let me ask it this way.</p> <p>17 Does it come packaged exactly in the way</p> <p>18 that it would be dispensed to the consumer, or does</p> <p>19 it come in a large bottle that allows a pharmacist</p> <p>20 to put it in bottles in smaller quantities when</p> <p>21 they're purchased by consumers?</p> <p>22 A. Both. Sometimes the pharmacy order in</p> <p>23 quantities of 30s or 90s, which, in most cases, it's</p> <p>24 a one -- once a day -- so it would be, like, a</p> <p>25 three-month or a one-month supply, and sometimes</p>	<p>Page 45</p> <p>1 just for the record.</p> <p>2 And if we go up to the top of this page,</p> <p>3 you'll see that this is a document that is supposed</p> <p>4 to provide inventory for HP1 operations.</p> <p>5 Can you tell me what HP1 operations is?</p> <p>6 A. It's not retail pharmacy. That's -- I don't</p> <p>7 know. I'm going to make an assumption that's Humana</p> <p>8 pharmacy mail operations, but that's not us.</p> <p>9 Q. Got it. Okay. Well, let's just go through</p> <p>10 these fields, and you can tell me if they're the</p> <p>11 same on the retail pharmacy side. Okay?</p> <p>12 You'll see here that under -- there's a</p> <p>13 bunch of acronyms, and there's a bunch of</p> <p>14 descriptions if we scroll down a little bit on this</p> <p>15 first page here. There we go.</p> <p>16 So as we've talked about, NDC code is the</p> <p>17 National Drug Code, and that is something that the</p> <p>18 retail pharmacies track, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. We talked about the lot number. That</p> <p>21 is not something that is tracked at the retail</p> <p>22 level, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. All right. There's a bunch of other fields</p> <p>25 on here, UOU, LDU. Are you familiar with these</p>

<p>Page 46</p> <p>1 terms?</p> <p>2 A. I know what unit of use is. Well, I know</p> <p>3 what unit of use is for a different company. I</p> <p>4 don't know what unit of use is for Humana. How</p> <p>5 about that?</p> <p>6 Q. Okay. What does it mean generally?</p> <p>7 A. So in -- so in my past experiences, when you</p> <p>8 are setting up the locations of a -- of a pharmacy</p> <p>9 and what goes in what areas, unit of use is</p> <p>10 something that would just -- you would grab</p> <p>11 something that's prefilled to the correct amount.</p> <p>12 Let's just say if it was 90 pills or</p> <p>13 something, and it's in a 90-pill bottle, then it's</p> <p>14 easy to grab that and label it and send it out</p> <p>15 without having to do too much more. In other words,</p> <p>16 you don't have to count out of -- out of a bottle of</p> <p>17 1,000, you don't -- I don't have to count out 90</p> <p>18 because it's already prepacked at that 90 level.</p> <p>19 Again, that's my understanding for other</p> <p>20 organizations, not for Humana, so that's my</p> <p>21 assumption.</p> <p>22 Q. All right. Are you familiar in -- for</p> <p>23 Humana's purposes with any of the other terms in</p> <p>24 this table here?</p> <p>25 A. No.</p>	<p>Page 48</p> <p>1 parent company?</p> <p>2 A. So -- so I would assume so. I don't -- I</p> <p>3 don't know. No. I guess you're -- are you asking</p> <p>4 me if someone from -- if someone from Humana had a</p> <p>5 conversation with someone from Amerisource? Is that</p> <p>6 what you're asking me, about this recall?</p> <p>7 Q. Well, so Humana has designated three</p> <p>8 witnesses to testify about the subjects in our</p> <p>9 30(b)(6) notice. What I'm trying to figure out is</p> <p>10 which of you -- which of the three of you is the</p> <p>11 right person to talk about this recall.</p> <p>12 A. Got it. In regards to conversations between</p> <p>13 Humana and Amerisource, not it, not me.</p> <p>14 Q. Okay.</p> <p>15 MS. GOLDENBERG: I hope, then, that when we</p> <p>16 get to one of the other two, someone is going to</p> <p>17 say that that's me. Is that fair, Kirstin? Yes?</p> <p>18 MS. IVES: Yeah, that's fine, but I would --</p> <p>19 I would say Mr. Cedeno might be able to talk</p> <p>20 about the interaction post-recall, not when the</p> <p>21 recall started, but, you know, to the extent --</p> <p>22 returns and things like that from the store</p> <p>23 level, that might be within his wheelhouse.</p> <p>24 MS. GOLDENBERG: All right. So we'll get to</p> <p>25 that part. Let's see. And -- well, strike that.</p>
<p>Page 47</p> <p>1 Q. Okay. Let's take this one down.</p> <p>2 All right. So let's talk about the recall a</p> <p>3 little bit. You said that you don't recall exactly</p> <p>4 who told you about the recall. How did you</p> <p>5 personally find out about it?</p> <p>6 A. So our recall process back then, very</p> <p>7 similar to how it is today, someone from</p> <p>8 professional practice will e-mail the associate</p> <p>9 directors of retail pharmacy, explaining the recall</p> <p>10 and explaining our steps.</p> <p>11 So essentially it would come to us via</p> <p>12 e-mail, and then from there, we have a -- steps that</p> <p>13 we take on our side to ensure that we are in</p> <p>14 compliance with that.</p> <p>15 Q. All right. Did you have any personal</p> <p>16 contact with representatives of AmerisourceBergen</p> <p>17 concerning the valsartan recall?</p> <p>18 A. No.</p> <p>19 Q. Okay. Did Humana Retail Pharmacy have any</p> <p>20 contact with -- well, let -- yeah. Let's just start</p> <p>21 this at a general level. Did anyone at Humana</p> <p>22 Retail Pharmacy have any contact with anyone at</p> <p>23 AmerisourceBergen concerning the recall?</p> <p>24 A. To my knowledge, no.</p> <p>25 Q. Okay. So that was all done through the</p>	<p>Page 49</p> <p>1 You know, why don't we take a five-minute</p> <p>2 break. In light of what we've gotten so far, I</p> <p>3 think I can cut down a lot of what I was going to</p> <p>4 ask today, and so this will give me some time to</p> <p>5 do a little consolidation.</p> <p>6 THE VIDEOGRAPHER: The time right now is</p> <p>7 9:57 a.m. We're off the record.</p> <p>8 (Recess from 9:57 a.m. until 10:11 a.m.)</p> <p>9 THE VIDEOGRAPHER: The time right now is</p> <p>10 10:11 a.m. We're back on the record.</p> <p>11 MS. GOLDENBERG: All right. So why don't we</p> <p>12 pull up Tab 44, then, please, and this will be</p> <p>13 Exhibit 7.</p> <p>14 (Humana - Cedeno Exhibit 7 was marked for</p> <p>15 identification.)</p> <p>16 BY MS. GOLDENBERG:</p> <p>17 Q. All right. Mr. Cedeno, it's my</p> <p>18 understanding that every patient who gets a -- or</p> <p>19 who filled a prescription of valsartan with Humana</p> <p>20 pharmacy received a patient insert with that</p> <p>21 prescription; is that right?</p> <p>22 A. That's correct.</p> <p>23 Q. And with that patient insert, it was --</p> <p>24 well, can you tell me how that was generated?</p> <p>25 A. So the ones we use in retail pharmacy is</p>

<p style="text-align: right;">Page 50</p> <p>1 very similar to the one that you have showing. It's 2 not the exact same one. That's a mail order one. 3 However, it is generated through the dispensing 4 system in retail pharmacy. 5 So we use a system called QS1 as our 6 dispensing system. It handles everything from our 7 inventory and dispensing, integration with 8 Surescripts so that we receive the prescriptions 9 electronically from the providers and so forth. 10 It's my understanding that within that 11 system, they have a link -- they link the most 12 up-to-date information of the medication so that 13 when, let's say, in this case, valsartan was 14 dispensed, then a patient information on valsartan 15 would print out with it, too, as well. It's 16 actually on the same leaflet for us in retail 17 pharmacy. 18 Q. All right. And so all the Humana entities 19 would coordinate so that patients would receive the 20 same information in their package insert, right? 21 A. We get the -- we get the information from 22 the same place, so, yes. 23 Q. Okay. And when you say you get the 24 information from the same place, is that the 25 FDA-approved label?</p>	<p style="text-align: right;">Page 52</p> <p>1 insert for valsartan, correct? 2 A. That's correct, yes. 3 Q. I won't take it personally that you're not 4 in Minnesota. 5 And so let's just scroll down on this a 6 little bit. You'll see here on the top of the page 7 that the generic name listed is valsartan tablets, 8 right? 9 A. Yes. 10 Q. Okay. Let's scroll down a little bit here 11 and you'll see that this says: Important 12 information from your Humana -- Humana pharmacy 13 team. 14 And we'll keep scrolling down. All right. 15 Now, here, it looks like this is a -- I don't know 16 if this was a sample or if this was for an actual 17 patient, but it says their date of birth is 18 2/10/1000. 19 So can I assume that this is a template? 20 A. I think it's a safe assumption. 21 Q. Okay. Nobody who was born in 1000 is still 22 alive today, right? 23 A. Yeah. No. 24 Q. All right. So let's scroll down a little 25 bit so we can see the bottom half of this page, and</p>
<p style="text-align: right;">Page 51</p> <p>1 A. I believe so. I don't know -- I don't 2 know -- I guess we'd have to defer to the systems 3 that we use. In this case, for retail pharmacy, QS1 4 would gather that information for us and spit the 5 label out, so to speak, once something is prepared 6 for that particular product. 7 Q. All right. Suffice it to say, QS1 would 8 have been the system that was used to generate the 9 patient insert for all valsartan prescriptions the 10 whole time that they were being sold, correct? 11 A. In the retail pharmacy, yes. 12 Q. Okay. And also that system would have spit 13 out the exact same patient insert to every patient 14 who purchased valsartan no matter where they lived, 15 right? 16 A. In retail pharmacy, yes. 17 Q. So a patient in Minnesota gets the same 18 package insert as a patient in Mississippi, for 19 example, right? 20 A. If we had retail pharmacy locations in those 21 states, yes, but we don't, but I get where you're 22 going. 23 Q. Fair enough. I guess I managed to choose 24 the two where you don't have them, but every retail 25 pharmacy would give every patient the same package</p>	<p style="text-align: right;">Page 53</p> <p>1 what you'll see here is that you've got the name of 2 the dispensed drug, and then you have some 3 information that says -- 4 MS. GOLDENBERG: Stop scrolling. 5 Q. At the top of this page it says: You have a 6 right to know about the proper use of your 7 medication and its effects. Written information 8 about this medicine has been provided to you. 9 Do you see that? 10 A. Yes. 11 Q. And when it says that, the written 12 information that's being provided to the patient is 13 exactly what's printed in a leaflet like this, 14 right? 15 A. That's correct. 16 Q. Is there any other information that Humana 17 Retail Pharmacy would provide to patients outside of 18 this package insert? 19 A. For valsartan or for any drug? 20 Q. For valsartan. 21 A. No. 22 Q. Okay. And so everything that would have 23 been provided to patients about valsartan would be 24 in this document and nowhere else, right? 25 A. Correct.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. Okay. In this document -- you can take a 2 look at the whole thing if you want, but my 3 understanding is that there are no mentions of 4 nitrosamines; is that right? 5 A. Looking at the page in front of me right 6 now, I would say there's no information right there 7 on -- 8 MS. GOLDENBERG: All right. And just to -- 9 A. -- nitrosamines. 10 MS. GOLDENBERG: Just to make this easy, 11 Leah, if you can pull up a Control F on this and 12 type in the word "nitrosamine," please. 13 Q. We'll see how long this takes. I'll 14 represent to you I did this off the record and got 15 no results. Okay. 16 A. I would think -- I would think there's no 17 information there. So, yeah, it says zero. 18 Q. There we go. 19 MS. GOLDENBERG: And if we do the same thing 20 with the word "NDMA." 21 A. I would assume it's not in there, either. 22 Q. Okay. So that one turned around real quick. 23 So suffice it to say, the package insert 24 given to patients about valsartan had no mention of 25 nitrosamines or NDMA in it, right?</p>	<p style="text-align: right;">Page 56</p> <p>1 A. No. 2 Q. I'm sorry. That was no? 3 A. Correct, it was no. No. 4 Q. Okay. Sorry. You cut out there for a 5 minute. 6 And when Humana sent out a recall notice to 7 its customers, what did it direct its customers to 8 do with their recalled valsartan? 9 A. When Humana Retail Pharmacy received the 10 recall notice, we called every single customer who 11 had been indicated in our records of receiving that 12 particular NDC. We asked them to bring it back 13 because we figured -- once we had the information 14 from our professional practices to which alternate 15 therapies we recommend switching them over to. 16 Yeah. 17 Q. Got it. And just to piggyback on to 18 something you just said, the recall at the Humana 19 level was done on an NDC level basis, right? 20 A. That's correct, yes. 21 Q. Okay. 22 A. We don't -- we don't -- we don't track lots 23 or batches, since we -- so we just went strictly on 24 NDCs. 25 Q. All right. And you also mentioned that</p>
<p style="text-align: right;">Page 55</p> <p>1 A. That's correct. 2 Q. Okay. 3 MS. GOLDENBERG: You can take that document 4 down, please. 5 Q. Let's talk a little bit about Topic 7, which 6 is your retention, sequestration, return, or 7 destruction of the valsartan drugs after their 8 recall. 9 What steps did Humana Retail Pharmacy take 10 to retain or return recalled valsartan? 11 A. So if we received notification from 12 Amerisource to return back to them, then we followed 13 that. If not, then we have a separate process where 14 we would -- we would quarantine whichever 15 medications were indicated in the recall so that 16 they are not dispensed to any other patients, and 17 then we would follow another process where we would 18 send it to a reverse distributor for destruction. 19 Q. Okay. And specifically with valsartan, what 20 happened here? 21 A. To my knowledge, a majority, if not all, 22 were sent back to Amerisource. 23 Q. All right. Does Humana Retail Pharmacy 24 currently have any recalled valsartan in its 25 possession?</p>	<p style="text-align: right;">Page 57</p> <p>1 Humana Retail Pharmacy no longer has any valsartan 2 in its possession. Did all of it get sent back to 3 AmerisourceBergen, or was some of it destroyed? 4 A. I believe a majority was sent back to 5 Amerisource. I can probably say there's a couple 6 one-offs that got sent back to PharmaLink, who's our 7 reverse distributor for destruction. 8 Q. Okay. Did Humana Retail Pharmacy request 9 any credits or refunds from AmerisourceBergen for 10 returning the recalled valsartan? 11 A. I believe Dan, tomorrow, can probably talk 12 about that. I don't -- I don't know. 13 Q. Okay. 14 MS. GOLDENBERG: And, Kirstin, is that 15 right, that he's going to be the right person to 16 ask about this? 17 MS. IVES: Yeah. Nathan may actually know a 18 little bit about that, too. 19 MS. GOLDENBERG: Okay. As long as you tell 20 me there's someone, then we can skip over that 21 today. 22 BY MS. GOLDENBERG: 23 Q. And let me see if I can short-circuit some 24 of this questioning. 25 Are you the right person to talk to about</p>

<p style="text-align: right;">Page 58</p> <p>1 any credits or refunds in any capacity whatsoever?</p> <p>2 A. Probably not. I can tell you that we do get</p> <p>3 credits and refunds. I can't tell you specifically</p> <p>4 if we requested it. I know that when we send back</p> <p>5 things to Amerisource, we are credited for them. So</p> <p>6 I don't know if that helps. Is that helpful at all?</p> <p>7 Q. Let me ask it this way. If Humana Retail</p> <p>8 Pharmacy wanted to know if it had received credits</p> <p>9 or refunds, is there a report that Humana could run</p> <p>10 that would be drug-specific that would tell you</p> <p>11 that?</p> <p>12 A. Maybe in accounting. I know stores -- when</p> <p>13 they receive credit for something, the stores get a</p> <p>14 notice or a credit memo that they keep in their</p> <p>15 store records. So whenever they do send something</p> <p>16 back to Amerisource, they get a record saying, yes,</p> <p>17 here's the dollar amount you were credited for for</p> <p>18 the quantity you sent back. Again, that's kept in</p> <p>19 the store level, so each individual store would</p> <p>20 maintain their own.</p> <p>21 Q. Okay. So the data exists. You just don't</p> <p>22 know the intricacies of it today. Is that fair?</p> <p>23 A. That's fair.</p> <p>24 MS. GOLDENBERG: Okay. All right. Why</p> <p>25 don't we pull up Tab 16, please, and this will be</p>	<p style="text-align: right;">Page 60</p> <p>1 It's easier for -- it's easier for us to</p> <p>2 order from Amerisource because our systems are --</p> <p>3 they talk to each other better, if that makes sense.</p> <p>4 So in regards to not getting a nasty e-mail from</p> <p>5 accounting, it's better to go through Amerisource</p> <p>6 than anyone else.</p> <p>7 Q. Okay. So what I'm trying to figure out is,</p> <p>8 are you the right person to ask about or if -- it</p> <p>9 looks like -- since you testified earlier that all</p> <p>10 of the retail pharmacy product came from</p> <p>11 Amerisource, would it be fair to assume that this is</p> <p>12 product that went to the other parts of the Humana</p> <p>13 pharmacy?</p> <p>14 A. Looking at the address, I believe that's one</p> <p>15 of our Humana Retail Pharmacies. It's not the one</p> <p>16 that I supervise, so it looks like that would come</p> <p>17 to a Humana Retail Pharmacy.</p> <p>18 Q. Okay. So this -- so you're the right person</p> <p>19 for this document then?</p> <p>20 A. Probably. Out of the three of us, yes.</p> <p>21 Q. Okay. So I just want to walk through the</p> <p>22 information here and confirm that this is all</p> <p>23 accurate. This should be pretty quick.</p> <p>24 Customer number, would those various numbers</p> <p>25 there refer to the different retail pharmacies?</p>
<p style="text-align: right;">Page 59</p> <p>1 Exhibit 8.</p> <p>2 (Humana - Cedeno Exhibit 8 was marked for</p> <p>3 identification.)</p> <p>4 MS. GOLDENBERG: All right. Let's scroll</p> <p>5 down to the bottom of the first page so we can</p> <p>6 get the Bates number, and you'll see this is</p> <p>7 HUM000150.</p> <p>8 Let's scroll back up to the top of this</p> <p>9 page, please.</p> <p>10 BY MS. GOLDENBERG:</p> <p>11 Q. You'll see that this is a report generated</p> <p>12 by a company called Anda. Are you familiar with</p> <p>13 Anda?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And what is that?</p> <p>16 A. Anda is our probably tertiary distributor of</p> <p>17 generic products.</p> <p>18 Q. And would Anda be a distributor that would</p> <p>19 be used by the retail pharmacy wing of Humana?</p> <p>20 A. Yeah. Again, it would be, like our</p> <p>21 tertiary. So if we -- normally it would be</p> <p>22 Amerisource, and then we would probably go to</p> <p>23 Cardinal, and then we would probably go to Anda, and</p> <p>24 then probably to Solco, if Amerisource was unable to</p> <p>25 get a product.</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Those numbers don't look familiar to me. I</p> <p>2 don't -- I don't -- I don't know.</p> <p>3 Q. Okay. Customer name, Humana --</p> <p>4 A. I would --</p> <p>5 Q. Sorry. Go ahead.</p> <p>6 A. No. I would assume that it probably is an</p> <p>7 indication of different retail pharmacies. We do</p> <p>8 have different customer numbers, I guess you could</p> <p>9 say, in between whether it's Amerisource or Anda or</p> <p>10 Cardinal or anyone else.</p> <p>11 Q. All right. You'll see, if you look at some</p> <p>12 of the numbers, for example, the number 308002</p> <p>13 appears multiple times on this first page. So would</p> <p>14 it be safe to assume that all of those orders are</p> <p>15 for all one retail pharmacy in a certain location?</p> <p>16 A. That would be my assumption.</p> <p>17 Q. Okay. We then have different customers, and</p> <p>18 all of them, at least on this page, appear to be the</p> <p>19 same, except Humana Medical Plan, Inc. is listed</p> <p>20 once. What is Humana Medical Plan, Inc.?</p> <p>21 A. I don't know. I know that when we -- I know</p> <p>22 that, let's say -- so I'm not too familiar with</p> <p>23 Anda, to be -- to be honest. However, in</p> <p>24 Amerisource, we have different names for all of our</p> <p>25 pharmacies, and sometimes they're just named Humana,</p>

<p style="text-align: right;">Page 62</p> <p>1 and sometimes they're named, you know, various 2 different names. Whoever sets up the accounts for 3 us picks and chooses whatever name they want to use. 4 Q. Sure. All right. Let's go to -- so it 5 looks like this is a report that was generated for 6 Humana by Anda; is that right? 7 A. That's what it looks like to me. 8 Q. Okay. And it covers the time period January 9 1st, 2013 to December 31st, 2019, right? 10 A. That's correct. 11 Q. All right. You said based on the billing 12 address, you assume that this is a retail pharmacy. 13 Can you tell from what you've seen so far whether 14 this would cover multiple retail pharmacies or if 15 this just covers a specific one? 16 A. It's interesting because it has -- it has 17 that address there as one of our pharmacies in 18 Plantation, Florida, but it has a different customer 19 number there, so I don't -- I don't know. 20 Q. All right. Either way, if Humana Retail 21 Pharmacy wanted to know -- or wanted to generate a 22 report with all of the valsartan that it had 23 purchased from Anda, is that something that could be 24 done on the Humana side, either in the aggregate or 25 on a pharmacy-by-pharmacy level?</p>	<p style="text-align: right;">Page 64</p> <p>1 those numbers refer to. 2 A. I don't know. There's no other, like, 3 description next to that. It just says Units_Net. 4 I would assume the number 24, the first number, 5 refers to number of bottles since I've never seen 6 a -- valsartan coming -- coming from a manufacturer 7 with a 24 in a bottle. It's usually 30, 90, 100, 8 500, 1,000. 9 Q. And when you say bottles, are those the bulk 10 bottles from the manufacturer or the individually 11 packaged bottles? 12 A. Again, to me, that makes -- that's the same 13 statement. So an individually packed bottle from 14 the manufacturer would come in a 30, 60 -- sorry -- 15 30, 90, 100, 500, 1,000 count prepackaged from the 16 manufacturer. 17 Q. I've got to get better at asking this. When 18 it says 24 units, is that 24 very large bottles that 19 the pharmacy would then repackage into smaller 20 bottles that go to the consumer, or are those 24 21 bottles filled with 30, 60, or 90 that are not 22 touched by the pharmacy and sold directly to the 23 consumer? 24 A. They could be any of those. It doesn't -- 25 it doesn't give me a description as to the four --</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Each individual pharmacy would have purchase 2 invoices, I guess, from Anda if they did purchase 3 from Anda, so, yes, they could. 4 From an aggregate level, probably. I don't 5 know. I'm -- that's not my area. 6 Q. Sure. And that would also be true for other 7 distributors, like AmerisourceBergen, right? 8 They -- each individual pharmacy would have records 9 that showed which valsartan was purchased? 10 A. Yes, correct. 11 Q. And as we discussed, that would have at 12 least, at minimum, the NDC information for those 13 drugs, right? 14 A. That's correct. 15 Q. All right. Let's go to the next page of 16 this document. Oh, sorry. Let's go to Page 14. 17 So this is the last page here, and you can 18 see that there's a table, and it says Units_Net and 19 Net_Sales_Amount. 20 Do you see that? 21 A. Yes. 22 Q. Now, the Net_Sales_Amount is redacted, but 23 under Units_Net there are a series of numbers there, 24 and I'm just wondering if you can tell me if those 25 are numbers of pills, numbers of packages, or what</p>	<p style="text-align: right;">Page 65</p> <p>1 the four different things, the four different 2 numbers, 24, 431, 350, and 2.4 million. 3 Q. Okay. Now, there's 2 million -- there's a 4 roughly 2.4 million number at the bottom there. 5 Do you see that? 6 A. Yes. 7 Q. Do you have an understanding of what that 8 refers to? 9 A. No. 10 Q. Okay. Let's go to Page 3, and what we see 11 here is we have the item generic name and the brand. 12 Do you see that? 13 A. Yes. 14 Q. All right. And by the way, valsartan is the 15 generic version of Diovan, correct? 16 A. That's correct. 17 Q. All right. And you would agree that it's 18 important for patients or customers of Humana to 19 understand that the generic drugs they're getting 20 were supposed to be the same, at least from a 21 therapeutic standpoint, as the reference listed drug 22 or the brand name drug, right? 23 A. Ask that again. I'm sorry. 24 Q. It was a long question. 25 You agree that patients who purchase generic</p>

<p style="text-align: right;">Page 66</p> <p>1 drugs from Humana would want to be sure that the 2 drugs they were getting were therapeutic equivalents 3 of the brand name drug, right? 4 MR. REEFER: Same objection. 5 A. Sometimes the providers just write 6 valsartan. They don't -- they don't say -- you 7 know, give the generic of Diovan HCT, so, yes -- yes 8 and no. I mean, something that's been a generic for 9 so long a time, a lot of time the providers, whether 10 that's a physician or a nurse practitioner or a 11 physician assistant, they will just write the 12 generic name for it, period, without really saying 13 it. 14 So it depends -- I guess it depends on each 15 patient's specific case, if they had that 16 conversation with their provider saying, "Yes, I'm 17 going to write you a prescription for Diovan HCT," 18 versus "I'm going to give you a prescription for 19 valsartan." So it doesn't matter, I guess. It does 20 matter. I don't know. 21 Q. Let me ask it in a different way. 22 A generic version of a drug is supposed to 23 be therapeutically equivalent to a brand name drug, 24 right? 25 MR. REEFER: Object to form.</p>	<p style="text-align: right;">Page 68</p> <p>1 MS. GOLDENBERG: Okay. We can take this one 2 down. 3 And let's put up Tab 38, which will be 4 Exhibit 9. 5 (Humana - Ceden Exhibit 9 was marked for 6 identification.) 7 MS. GOLDENBERG: For the record, this is 8 HUM000990. 9 BY MS. GOLDENBERG: 10 Q. And you'll see that is the title Humana 11 Transaction History Log. 12 Do you see that? 13 A. Yes, I do. 14 Q. All right. Is this a report that might be 15 generated by the retail pharmacy? 16 A. It does not look like one, no. 17 Q. Okay. So this is something I should ask one 18 of your colleagues about? 19 A. Yes. 20 MS. GOLDENBERG: Okay. Kirstin, you agree 21 with that? 22 MS. IVES: Yes. Mr. Hunnell. 23 MS. GOLDENBERG: Okay. All right. Let's 24 take this one down, then, and let's put up Tab 25 17, which will be Exhibit 10.</p>
<p style="text-align: right;">Page 67</p> <p>1 A. Yes. Correct. 2 MR. REEFER: Foundation. 3 Q. All right. And so if a patient either was 4 written a prescription for or is given a substitute 5 for the brand name of Diovan, any patient filling a 6 prescription for valsartan is going to have an 7 expectation, and reasonably so, that the drug is 8 going to work just as well as Diovan, right? 9 MR. REEFER: Object to form and foundation. 10 A. Yes, correct. 11 Q. Okay. All right. So on Page 3 here, it 12 looks like, again, the NDC code is tracked, and 13 there's a subject header for Form. 14 Do you know what that refers to? 15 A. It looks like tablet, TB for tablet. 16 Q. Ah, I see. Okay. Let's go to Page 5, and 17 here, as we've discussed, the name of the 18 manufacturer of the drug does look like it's 19 tracked, right? 20 A. Yes, it looks like it. 21 Q. And so we know from looking at this page 22 that, at a minimum, we understand Humana Retail 23 Pharmacy purchased drugs that were manufactured by 24 Aurobindo, Teva, and Solco, correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 69</p> <p>1 (Humana - Ceden Exhibit 10 was marked for 2 identification.) 3 BY MS. GOLDENBERG: 4 Q. Tab 17 -- so this is another spreadsheet 5 here, and you'll see that at the top, we've got the 6 NDC code information written three different ways. 7 And if we go down to the next page -- oh, no. 8 Sorry. Let's go to the last page. 9 All right. So here we have a number of 10 other suppliers that are listed, and all of these 11 appear to be suppliers of valsartan that -- well, 12 I'll just leave it there. 13 Does that look right to you? 14 MR. REEFER: Object to form and foundation. 15 A. It looks like it to me, yes. 16 Q. Okay. And so we can see here that Humana 17 purchased drugs that were made by Actavis, 18 Aurobindo, Mylan, and Teva, correct? 19 MR. REEFER: Same objection. 20 A. If that's a supplier, I would assume so, 21 yes. This is -- this is probably -- I'm not so sure 22 this includes Humana Retail Pharmacy or not, since 23 we don't -- we don't go directly to the manufacturer 24 to purchase. We usually just go through Amerisource 25 or, like we saw before, through Anda or through</p>

<p style="text-align: right;">Page 70</p> <p>1 Cardinal.</p> <p>2 So a direct buy from the manufacturer would</p> <p>3 not be something that retail pharmacy does. So I'm</p> <p>4 not too sure, again, if it's -- it includes retail</p> <p>5 pharmacy, but that's what it appears like to me,</p> <p>6 that the supplier was directly those listed.</p> <p>7 Q. Okay. Do you have an understanding of what</p> <p>8 SmartSource or Bellco is?</p> <p>9 A. Yeah. Bellco is also another supplier. As</p> <p>10 you can see, it's owned by Amerisource, ABC.</p> <p>11 Q. Right.</p> <p>12 A. And we do get some -- we do get some</p> <p>13 generics from there from time to time. It's very</p> <p>14 rare in Humana Retail Pharmacy that we go through</p> <p>15 that, but it's there as an option for us.</p> <p>16 Q. Okay. It was something that Humana Retail</p> <p>17 Pharmacy used, though?</p> <p>18 A. For valsartan?</p> <p>19 Q. Yes.</p> <p>20 A. If it shows up on this list, potentially,</p> <p>21 yes. I don't -- I don't -- without looking at</p> <p>22 anything that shows my purchase order from Bellco, I</p> <p>23 couldn't be 100 percent confident.</p> <p>24 Q. All right. Either way, whether Humana</p> <p>25 Retail Pharmacy went directly through</p>	<p style="text-align: right;">Page 72</p> <p>1 consumers who had recalled valsartan. Did Humana</p> <p>2 provide any credits or refunds to those consumers?</p> <p>3 A. Yes. To my knowledge, when -- and we took</p> <p>4 back -- medications that were recalled, we find them</p> <p>5 an alternate product to give, and once we do that,</p> <p>6 we figure out a way to give them the credit back for</p> <p>7 it, you know.</p> <p>8 We cannot, I guess, double bill for</p> <p>9 something. We would have to reverse one of the</p> <p>10 claims and then credit that forward to the new copay</p> <p>11 that came forward. So if there was a copay, there</p> <p>12 was a dollar amount credit moved forward to cover</p> <p>13 the new replacement, if that makes sense.</p> <p>14 Q. I think so. Let's just break it down a</p> <p>15 little bit and walk me through the actual</p> <p>16 documentation process for this.</p> <p>17 So a patient comes back, brings in their</p> <p>18 recalled valsartan. What does someone at Humana do</p> <p>19 with that?</p> <p>20 A. Someone in Humana Retail Pharmacy would --</p> <p>21 had that out -- either had the outbound call to the</p> <p>22 patient saying, "Mr. or Mrs. So-and-So," you know --</p> <p>23 and they had a verbiage that we -- that we</p> <p>24 recommended to them about the -- about the recall.</p> <p>25 Once the patient brought back that -- let's</p>
<p style="text-align: right;">Page 71</p> <p>1 AmerisourceBergen or went through Bellco, the data</p> <p>2 about what was purchased would still exist at every</p> <p>3 retail pharmacy, correct?</p> <p>4 A. Each individual pharmacy would have their</p> <p>5 records of where they purchased from, so whether it</p> <p>6 came from Amerisource or Bellco or Anda, yes.</p> <p>7 Q. All right. Let's go to Page 4, and this may</p> <p>8 be a better question for your colleagues, but I want</p> <p>9 to just run it past you and you can let me know.</p> <p>10 There's information here about warehouse use or</p> <p>11 warehouse.</p> <p>12 Do you see that?</p> <p>13 A. I do, yes.</p> <p>14 Q. All right. Is this information about where</p> <p>15 the product is warehoused something that would</p> <p>16 concern Humana Retail Pharmacy, or is this a</p> <p>17 question better posed to one of your colleagues?</p> <p>18 A. Probably one of my colleagues.</p> <p>19 Q. Okay.</p> <p>20 MS. IVES: And, Marlene, this a Dan question</p> <p>21 for tomorrow. These are the -- the purchasing</p> <p>22 records would fall under his department.</p> <p>23 MS. GOLDENBERG: All right. So let's take</p> <p>24 this one down. We'll save that for him.</p> <p>25 Q. Let's talk about credits or refunds for</p>	<p style="text-align: right;">Page 73</p> <p>1 say valsartan in this case, and we decided to, you</p> <p>2 know, talk to their provider and move them to a</p> <p>3 different product, we would say, you know, "Bring</p> <p>4 back your valsartan." We would reverse that claim</p> <p>5 to the insurance company or to the PBM.</p> <p>6 Once that claim was reversed, we would then</p> <p>7 reprocess the new prescription, and whatever that</p> <p>8 copay was for that, we would take the copay that</p> <p>9 they paid for the previous valsartan product and</p> <p>10 credit that towards the copay of the new product.</p> <p>11 So if it was in the same tier, let's just</p> <p>12 say, and let's just say the patient had a \$5 copay,</p> <p>13 we would take that \$5 and credit it towards the new</p> <p>14 \$5 copay so the patient is not out-of-pocket for</p> <p>15 anything. However, Humana does lose the</p> <p>16 reimbursement for the -- for the first product, if</p> <p>17 that makes sense.</p> <p>18 Q. Okay. And is that something that's done</p> <p>19 only if the product is returned?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And if the product is returned and</p> <p>22 someone transfers that copay amount over to the next</p> <p>23 drug, is that something that would be reflected in a</p> <p>24 record somewhere at Humana Retail Pharmacy?</p> <p>25 A. Inconsistently, yes. So if there was --</p>

<p style="text-align: right;">Page 74</p> <p>1 if -- we do have a place that we leave patient notes 2 within our QS1 system, and if the pharmacist said, 3 "Mrs. Smith brought in her valsartan and I credited 4 that towards her new lisinopril prescription," let's 5 just say, then that would pop up, but it wasn't a 6 standard practice back then for us to do. 7 Q. Well, so I'm sure we all have accountants 8 that we work with, and if an accountant finds a 9 penny missing, they're going to be upset, right? 10 A. Good question. So there -- we usually write 11 a handwritten note saying this was -- we're very 12 complicated -- a very handwritten note and then 13 place it in with our -- with our -- with our end of 14 day point of sale reports back to accounting. So 15 they do see that. It's a handwritten note, so, I 16 mean, very official. 17 Q. And what does the accountant do with those 18 handwritten notes? 19 A. I don't know. That's accounting. 20 Q. All right. 21 A. I -- I'm going to operate under the 22 assumption that they say, okay, this \$5 was used 23 towards this \$5 and that's why that checks out, so 24 there's a checks and balances, but, again, it's a 25 handwritten note, so I'm not too sure how deep they</p>	<p style="text-align: right;">Page 76</p> <p>1 person to ask about that? 2 A. Maybe. Not me. I don't -- let me think. 3 From a third-party payer? Possibly. I don't know. 4 I'm sorry. 5 Q. Okay. Well, let's talk about -- let's just 6 talk about the data itself. If a third-party payer 7 had come to Humana Retail Pharmacy and requested a 8 credit or refund, where would that be documented? 9 A. I don't know. 10 Q. Would it be documented? 11 A. I would assume so. If someone comes to us 12 looking for money, I'm sure it's documented 13 somewhere. 14 Q. All right. And if that money is actually 15 given out, would that be documented by the 16 accounting department? 17 A. I would assume so, yes. 18 Q. Okay. And would that documentation break 19 down exactly what the credit or refund was for? 20 A. I would assume so, yes. 21 Q. Okay. And do you have an understanding of 22 what the parameters were for issuing credits or 23 refunds for recalled valsartan? 24 A. No. 25 Q. Okay. And I guess I should have asked that.</p>
<p style="text-align: right;">Page 75</p> <p>1 dive in for \$5. I'm assuming, it's accounting, that 2 every penny does count, so I'm going to assume that 3 they do that check. 4 Q. All right. And, you know, if Humana ever 5 were to get audited, every penny has to be accounted 6 for as well, right? 7 A. That's correct. That's correct. Good 8 answer -- good question. 9 Q. Okay. And to make sure that that is 10 properly accounted for, presumably the accounting 11 department is entering in some note that reflects 12 that handwritten note in -- at least on their side 13 of things, right? 14 A. That's my assumption, yes. 15 Q. Okay. So at least at the accounting level, 16 there would be a record of credits that would be 17 given to consumers, right? 18 A. Yes. 19 Q. Okay. Let's talk about third-party payers 20 for a minute. Did Humana Retail Pharmacy issue any 21 credits or refunds in response to any requests for a 22 credit or a refund by a third-party payer for 23 valsartan? 24 A. I don't recall. 25 Q. Okay. Is one of your colleagues a better</p>	<p style="text-align: right;">Page 77</p> <p>1 Let me break that question down. 2 Do you have an understanding of what the 3 parameters were for giving credits or refunds to 4 consumers who purchased recalled valsartan? 5 A. If a consumer asked for a refund because of 6 a recalled product, then we give the credit back to 7 the patient as long as they -- when they bring back 8 the -- you know, the recalled product. 9 Q. Okay. So the parameters are, if you bring 10 it back, you get the credit or refund; if you don't, 11 then you don't get the credit or refund. Is that 12 right? 13 A. To my knowledge, yes, that's -- yeah. 14 Q. Okay. And for third-party payers, you -- do 15 you have an understanding of what the parameters 16 were for issuing credits or refunds for recalled 17 valsartan? 18 MS. GOLDENBERG: Bless you, Kirstin. 19 A. No, I don't. 20 Q. Okay. But either way, Humana Retail 21 Pharmacy does maintain, in its ordinary course of 22 business, records of credit or refunds given out and 23 the reasons for those, right? 24 A. Correct. 25 Q. Okay. And does the data generally reflect</p>

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<p>1 who received the credit or refund?</p> <p>2 A. I don't think so. So if I -- okay. Let</p> <p>3 me -- here's why I don't know. If a patient's</p> <p>4 representative comes back to ask for the refund, I</p> <p>5 don't -- there's no way for us to keep track of who</p> <p>6 that patient representative was. It would be, I</p> <p>7 guess, credited to the patient's account. Does that</p> <p>8 make sense?</p> <p>9 Q. Yeah. Okay. So if it's credited to the</p> <p>10 patient's account, then there is a record of which</p> <p>11 patient received a credit or refund, right?</p> <p>12 A. That's my understanding, yes.</p> <p>13 Q. Okay. And the credit or refund record would</p> <p>14 also show the amount of the credit or refund, right,</p> <p>15 because you already said your accounting department</p> <p>16 wants to know that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And would it also reflect the date</p> <p>19 that the credit or refund was processed?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. All right. So let's just talk names</p> <p>22 for a little bit and see if you can give me the</p> <p>23 information on who the right people are at the</p> <p>24 company to ask some follow-up questions if we ever</p> <p>25 have them.</p>	<p>1 they would ask their associate director. So in my</p> <p>2 area, they would ask me, and if I did not know or I</p> <p>3 needed clarification, I would ask our professional</p> <p>4 practice team and they would either have the answer</p> <p>5 or find the answer for us.</p> <p>6 Q. Okay. Who at the -- on the retail side of</p> <p>7 the company would be responsible for making sure</p> <p>8 that each of the brick-and-mortar locations knew</p> <p>9 about the valsartan recall?</p> <p>10 A. So each associate director would send the</p> <p>11 information out to their teams, and then we would</p> <p>12 follow up to ensure that they've completed the steps</p> <p>13 that we've asked them to do.</p> <p>14 MS. GOLDENBERG: All right. Why don't we</p> <p>15 take five or ten minutes. I'm just going to</p> <p>16 review my notes. I think I'm almost done.</p> <p>17 THE VIDEOGRAPHER: The time right now is</p> <p>18 10:51 a.m. We're off the record.</p> <p>19 (Recess from 10:51 a.m. until 11:00 a.m.)</p> <p>20 THE VIDEOGRAPHER: The time right now is</p> <p>21 11:00 a.m. We're back on the record.</p> <p>22 MS. GOLDENBERG: All right. Mr. Cedeno, I</p> <p>23 have no further questions. I appreciate your</p> <p>24 time today.</p> <p>25 THE WITNESS: Thank you.</p>
<p>1 Who or what person or department at the</p> <p>2 company on the retail side was primarily responsible</p> <p>3 for the purchase of valsartan?</p> <p>4 A. On the retail side? Each individual</p> <p>5 pharmacist in charge for that location would be</p> <p>6 responsible for the purchase of their valsartan</p> <p>7 products.</p> <p>8 Q. Okay. So it's the lead pharmacist at each</p> <p>9 of the retail pharmacies?</p> <p>10 A. Yes, unless they are on vacation, and then</p> <p>11 it would be someone who is covering for them, but,</p> <p>12 yes.</p> <p>13 Q. I suppose those are allowed sometimes,</p> <p>14 aren't they?</p> <p>15 Who was responsible for inventory</p> <p>16 maintenance, receiving and distributing the</p> <p>17 valsartan on the retail side?</p> <p>18 A. Each individual pharmacist and pharmacy</p> <p>19 technician in each individual location is</p> <p>20 responsible for maintaining their inventory.</p> <p>21 Q. Okay. And -- all right. If anybody on the</p> <p>22 retail side had questions about the valsartan</p> <p>23 recall, who would be responsible for making those</p> <p>24 inquiries?</p> <p>25 A. So if someone had a question about a recall,</p>	<p>1 THE VIDEOGRAPHER: The time right now is</p> <p>2 11:00 a.m. We're off the record.</p> <p>3 (Whereupon, the deposition concluded at</p> <p>4 11:00 a.m.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 CERTIFICATE</p> <p>2 I, Susan D. Wasilewski, Registered</p> <p>3 Professional Reporter, Certified Realtime Reporter,</p> <p>4 Certified Manager of Reporting Services, Certified</p> <p>5 Realtime Captioner, and Florida Professional</p> <p>6 Reporter, hereby certify that the witness named</p> <p>7 herein appeared via Remote Counsel/Zoom technology</p> <p>8 on Monday, September 27, 2021, and was duly sworn.</p> <p>9 I FURTHER CERTIFY that I was authorized to</p> <p>10 and did stenographically report the examination of</p> <p>11 the witness named herein; that a review of the</p> <p>12 transcript was requested; and that the foregoing</p> <p>13 transcript is a true record of my stenographic</p> <p>14 notes.</p> <p>15 I FURTHER CERTIFY that I am not related to</p> <p>16 or an employee of any of the parties, nor am I</p> <p>17 related to or an employee of any of the parties'</p> <p>18 attorneys or counsel connected with this action, nor</p> <p>19 am I financially interested in the outcome of this</p> <p>20 action.</p> <p>21 WITNESS my hand this 12th of October, 2021.</p> <p>22</p> <p>23</p> <p>24 Susan D. Wasilewski, RPR, CRR, CMRS, CRC, FPR</p> <p>25</p>	<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> <p>25</p>
<p>Page 83</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3</p> <p>4 Please read your deposition over carefully</p> <p>5 and make any necessary corrections. You should</p> <p>6 state the reason in the appropriate space on the</p> <p>7 errata sheet for any corrections that are made.</p> <p>8</p> <p>9 After doing so, please sign the errata sheet</p> <p>10 and date it. It will be attached to your</p> <p>11 deposition.</p> <p>12</p> <p>13 It is imperative that you return the</p> <p>14 original errata sheet to the deposing attorney</p> <p>15 within thirty (30) days of receipt of the deposition</p> <p>16 transcript by you. If you fail to do so, the</p> <p>17 deposition transcript may be deemed to be accurate</p> <p>18 and may be used in court.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 85</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do hereby</p> <p>4 acknowledge that I have read the foregoing pages, 1</p> <p>5 through 84, and that the same is a correct</p> <p>6 transcription of the answers given by me to the</p> <p>7 questions therein propounded, except for the</p> <p>8 corrections or changes in form or substance, if any,</p> <p>9 noted in the attached Errata Sheet.</p> <p>10</p> <p>11</p> <p>12 _____</p> <p>13 CESAR CEDENO DATE</p> <p>14 Corporate Representative for</p> <p>15 Humana Pharmacy, Inc.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20 Subscribed and sworn to before me this</p> <p>21 ____ day of _____, 20__.</p> <p>22 My Commission expires: _____</p> <p>23</p> <p>24 _____</p> <p>25 Notary Public</p>

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Exhibit 98

REDACTED

<p style="text-align: right;">Page 2</p> <p>1 ZOOM APPEARANCES: 2 3 GOLOMB & HONIK P.C. 4 BY: RUBEN HONIK, ESQ. 1835 Market Street Suite 2900 Philadelphia, Pennsylvania 19102 (215) 327-9166 ruben@honiklaw.com Representing the Plaintiffs 8 SLACK DAVIS SANGER, LLP 9 BY: JOHN R. DAVIS, ESQ. 6001 Bold Ruler Way Suite 100 Austin, Texas 78746 (512) 795-8686 jdavis@slackdavis.com Representing the Plaintiffs 13 KANNER & WHITELEY, LLC 14 BY: LAYNE HILTON, ESQ. 701 Camp Street New Orleans, Louisiana 70130 (504) 524-5777 lhilton@kanner-law.com Representing the Plaintiffs 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 4</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 3 DUANE MORRIS, LLP BY: COLEEN W. HILL, ESQ. 30 South 17th Street Philadelphia, Pennsylvania 19103 (215) 979-1164 cwhill@duanemorris.com Representing the Defendants, Zhejiang Huahai Pharmaceutical Co. Ltd., Princeton Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC 8 9 BARNES & THORNBURG, LLP BY: JOHN HEINZ, ESQ. 11 S. Meridian Street Indianapolis, Indiana 46204 (317) 231-6491 John.heinz@btlaw.com Representing CVS Pharmacy, Inc., and Rite Aid Corporation 13 14 FALKENBERG IVES, LLP BY: MEGAN A. ZMICK, ESQ. 230 W. Monroe Street, Suite 2220 Chicago, Illinois 60606 (312) 366-4808 Maz@falkenbergives.com Representing the Defendant, Humana 17 18 CROWELL & MORING, LLP BY: MIMI S. DENNIS, ESQ. 1001 Pennsylvania Avenue, NW Washington, D.C. 20004 (202) 624-2774 mdennis@crowell.com Representing the Defendants, Cardinal Health, Inc. 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 3 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP BY: CLEM C. TRISCHLER, ESQ. 4 BY: FRANK H. STOY, ESQ. One Oxford Centre, 38th Floor Pittsburgh, Pennsylvania 15219 (412) 263-1840 cct@pietragallo.com fhs@pietragallo.com 7 Representing the Defendant, Mylan Pharmaceuticals, Inc. 8 9 CIPRIANI & WERNER, P.C. BY: CAITLIN E. LAWLOR, ESQ. 450 Sentry Parkway, Suite 200 Blue Bell, Pennsylvania 19422 (610) 567-0700 Clawlor@c-wlaw.com 12 Representing the Defendants, Aurobindo Pharma, USA, Inc. and Aurolife Pharma, LLC 14 15 GREENBERG TRAURIG, LLP BY: STEVEN M. HARKINS, ESQ. Terminus 200 3333 Piedmont Road NE Suite 2500 Atlanta, Georgia 30305 (678) 553-2312 harkinss@gtlaw.com 18 Representing the Defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, and Actavis Pharma, Inc. 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 3 NORTON ROSE FULBRIGHT US LLP BY: ELLIE NORRIS, ESQ. 2200 Rose Avenue, Suite 3600 Dallas, Texas 75201 (214) 855-8000 ellie.norris@nortonrosefulbright.com 6 Representing the Defendant, McKesson Corporation 7 8 ULMER BERNE, LLP BY: JEFFREY D. GEOPPINGER, ESQ. 600 Vine Street Suite 2800 Cincinnati, Ohio 45202 (513) 698-5114 jgeoppinger@ulmer.com 11 Representing the Defendant, AmerisourceBergen Corporation 12 13 14 ALSO PRESENT: 15 VIDEOTAPE TECHNICIAN: Kristalyn Duran 16 17 Bradley Matta, Esq. Elana Williams, Esq. (Mylan - Viatris) 18 19 Beth Questad - Paralegal (Slack Davis) 20 21 22 23 24</p>

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I N D E X
- - -

Testimony of:
 By Mr. Honik S. WAYNE TALTON 13

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E X H I B I T S
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Mylan PL-Talton-5	E-mail Thread 4/1/15 Subject, Valsartan ROS MYLAN-MDL2875-00494035-37	235
Mylan PL-Talton-6	Drug Master File Valsartan USP 3.2.S.2 Manufacturing Process Development	241
Mylan PL-Talton-7	Letter, FDA to Mylan DMFDLAPI Information Request MYLAN-MDL2875-00552465	256
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Mylan PL-Owens-7	Cover Letter for Response to Information Request Letter 8/13/18 MYLAN-MDL2875-00345657	332
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2	EXHIBITS (Cont'd.)		
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4	NO.	DESCRIPTION	PAGE
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24			

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1 - - -

2 THE VIDEOGRAPHER: We are

3 now on the record. My name is

4 Kristalyn Duran, videographer for

5 Golkow Litigation Services.

6 Today's date is April 27,

7 2021, and the time is 9:13 a.m.

8 This deposition is being

9 held by remote Zoom in the matter

10 of Valsartan, Losartan, and

11 Irbesartan Products Liability

12 litigation.

13 The deponent today is Wayne

14 Talton.

15 All parties to this

16 deposition are appearing remotely

17 and have agreed to the witness

18 being sworn in remotely.

19 All appearances are noted on

20 the stenographic record.

21 Will the court reporter

22 please administer the oath.

23

24

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2	DEPOSITION SUPPORT INDEX	
3	---	
4		
5	Direction to Witness Not to Answer	
6	PAGE LINE	
7	None.	
8	Request for Production of Documents	
9	PAGE LINE	
10	None.	
11	Stipulations	
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14	Questions Marked	
15	PAGE LINE	
16	None.	
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1 - - -

2 ... S. WAYNE TALTON, having

3 been first duly sworn, was

4 examined and testified as follows:

5 - - -

6 EXAMINATION

7 - - -

8 BY MR. HONIK:

9 Q. Sir, good morning to you.

10 Can you hear my voice?

11 A. Yes, I can.

12 Q. And can you see my image?

13 A. Yes, I can.

14 Q. I heard Mr. Trischler and

15 others refer to you as Talton. Is that

16 the correct pronunciation of your last

17 name?

18 A. It's actually Talton. But

19 I'll answer to either.

20 Q. Okay. I appreciate that.

21 MR. TRISCHLER: My

22 apologies.

23 BY MR. HONIK:

24 Q. Having spent a lifetime of

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1 having my own last name mispronounced. I
2 appreciate where you're coming from,
3 Mr. Talton.
4 So as I think I said, my
5 name is Ruben Honik, and I'm one of the
6 plaintiffs' lawyers in this litigation
7 involving valsartan.
8 I don't know what screen
9 you're looking at. But there are
10 multiple lawyers present today in
11 connection with your testimony that
12 you're going to offer under oath.
13 A number of them represent
14 the plaintiffs' group, like myself. And
15 there are a great many defense lawyers
16 who represent some of the other
17 defendants in this lawsuit.
18 Do you understand that?
19 A. Yes.
20 Q. And I take it that you
21 understand that the oath that was just
22 administered and accepted by you, is the
23 same that you would give in a court of
24 law if you were giving testimony there;

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1 is that correct?
2 A. Yes.
3 Q. And in fact, have you given
4 testimony under oath before today?
5 A. Yes, I have.
6 Q. Have you done so in the
7 setting of a deposition like this one?
8 A. This is the first virtual
9 deposition that I've done. But I've done
10 many face-to-face.
11 Q. And apart from any live
12 depositions that you may have given in
13 the past, have you given testimony under
14 oath in any other settings, such as a
15 courtroom or a legislative body or
16 anything like that?
17 A. Yes, a couple of occasions.
18 Q. And what instances or
19 occasions were those?
20 A. I testified in a court
21 appearance related to a tax issue that
22 Mylan was undergoing a couple of years
23 ago. And then I've also appeared in
24 court for a deposition for a P-IV

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1 litigation.
2 Q. I'm sorry. For what kind of
3 litigation?
4 A. A Paragraph IV patent
5 certification litigation.
6 Q. Yep.
7 A. Patent challenge.
8 Q. Now, you used the word
9 deposition and court. Was it one or the
10 other? Were you in court?
11 A. Yes, I've appeared in court
12 twice.
13 Q. Okay. The first was the tax
14 issue. And the second was the patent
15 issue, correct?
16 A. Reverse order but those were
17 the two instances.
18 Q. Appreciate that.
19 And then the rest of the
20 occasions in which you've given testimony
21 under oath have been in depositions, and
22 every instance before today, live and in
23 person; is that correct?
24 A. That's correct.

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1 Q. And what kind of depositions
2 or what kind of matters did you give
3 testimony in a deposition setting prior
4 to today?
5 A. Patent litigation.
6 Q. In every instance?
7 A. Yes.
8 Q. And is that part of the
9 scope of your responsibility at Mylan or
10 perhaps now at Viatrix, to support the
11 company in patent litigation by
12 testimony?
13 A. If necessary based on my
14 current role.
15 Q. And I don't want to belabor
16 the point, but how many instances did you
17 give deposition testimony in patent
18 related matters?
19 A. I haven't counted them. But
20 it's probably close to 50 over my 20-year
21 career.
22 Q. And apart from the two court
23 appearances that you made and what sounds
24 like dozens of depositions that you've

Page 18

1 given, have you supplied testimony under
2 oath in any other setting at any other
3 time before today?
4 A. No.
5 Q. So Mr. Talton, the rules
6 today are substantially the same, I
7 promise you, relating to the previous
8 depositions that you've given with a
9 couple of rules that I want to emphasize
10 before we start as a matter of
11 housekeeping.
12 I hear you when you say this
13 is your first remote or virtual
14 deposition that you've taken.
15 And what that has meant for
16 those of us who have taken a great many
17 of these now, is that it's even more
18 important than ordinary to wait for the
19 speaker to complete his or her words or
20 statement before you supply an answer.
21 Do you understand that?
22 A. Yes.
23 Q. And the reason for that is
24 there's a bit of a delay on the computer

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1 through the internet. And we want to
2 ensure that our court reporter can hear
3 and then take down everything what each
4 of us says verbatim. Do you understand
5 that?
6 A. Yes.
7 Q. Now, that holds equally
8 true, Mr. Talton, when Mr. Trischler,
9 your very fine lawyer, places an
10 objection on the record.
11 So I want you to just
12 hesitate for maybe a second or so after a
13 question has been posed. And if you hear
14 him speaking up, it's to protect the
15 record by placing an objection of some
16 sort on the record.
17 The rules require that we do
18 so in an abbreviated fashion, so it
19 shouldn't take very long. But allow him
20 to complete that before you begin to
21 supply an answer.
22 Can you do that for me as
23 well?
24 A. Yes.

Page 20

1 Q. Another paramount rule,
2 Mr. Talton, is if I ask a question of you
3 which for any reason you haven't either
4 heard or understood, I'd instruct you not
5 to answer it in favor of asking me to
6 repeat or rephrase it so that you can
7 understand it. Can you do that for me?
8 A. Yes.
9 Q. And if you do supply an
10 answer, I will assume that you've
11 understood the question and are supplying
12 your best answer under oath. Is that
13 fair?
14 A. Yes.
15 Q. I've got quite a bit of
16 ground to cover with you. But I promise
17 to try to do it as expeditiously and
18 succinctly as possible.
19 I want to assure you that
20 this is not an endurance test for you. I
21 typically try to break for at least five
22 or 10 minutes every hour. And of course
23 we'll take a midday break at some point
24 for lunch.

Page 21

1 But if you need to break for
2 any reason at any time, you simply need
3 to let me know that. And once we've got
4 your response to any pending questions,
5 we can go on and take a break. Is that
6 okay with you?
7 A. Yes, that's fine.
8 Q. Now, before we begin in
9 Earnest, I understand from Mr. Trischler
10 that we're waiting for some copying of
11 records. Am I to understand that you've
12 got no records in front of you?
13 A. Not at this time.
14 Q. With your permission, I'm
15 going -- I've got your CV in front of me.
16 And I suspect even without looking at it
17 you probably have a pretty good handle on
18 its contents. Perhaps as I'm questioning
19 you, it will be placed in front of you.
20 But that's going to be Exhibit Talton-1
21 when it arrives.
22 And with your permission I
23 would like to ask you some questions
24 about your background. May I do that?

Page 22

1 A. Yes.
2 (Document marked for
3 identification as Exhibit
4 PL-Talton-1.)
5 BY MR. HONIK:
6 Q. In the -- well, let me note
7 that it states that you live in
8 Morgantown, West Virginia. Is that still
9 correct?
10 A. Yes.
11 Q. And do you work in
12 Morgantown as well?
13 A. Yes. I'm working remotely
14 now. But I have an office in
15 Morgantown.
16 Q. Are you currently employed
17 by Viatrix?
18 A. Yes.
19 Q. And prior to that, of
20 course, you were employed by Mylan?
21 A. That's correct.
22 Q. And you've been exclusively
23 employed by Mylan since 2001; is that
24 correct?

Page 23

1 A. That's correct.
2 Q. And I gather you've held a
3 variety of positions within the
4 regulatory affairs department throughout
5 those years; is that correct?
6 A. Yes.
7 Q. And outside of the
8 regulatory affairs department, you've had
9 no other formal titles or positions,
10 correct?
11 A. My entire career at Mylan
12 has been in regulatory affairs.
13 Q. Thank you.
14 Now, the resumé that I have
15 has a summary at the beginning of it
16 after your contact information, which
17 reads as follows?
18 "A results-oriented
19 regulatory affairs professional with over
20 32 years of diverse development and
21 regulatory affairs experience within the
22 pharmaceutical industry."
23 Let me stop there.
24 Are those words that you

Page 24

1 wrote?
2 A. Yeah.
3 Q. Okay. And as of whenever
4 this document was created, your CV, it
5 indicates that you had 32 years of
6 experience. But judging by the years on
7 this resumé, it appears this resumé may
8 be as much as eight years old, do you
9 know; is that correct?
10 A. That's very possible. I
11 supplied my current CV. I haven't
12 updated it in some time.
13 Q. Okay. So is it correct that
14 perhaps as of today you've been a
15 regulatory affairs professional for
16 actually 40 years? Would that be fair?
17 A. I joined regulatory affairs
18 in 1991 at GSK. I've been in a
19 regulatory affairs role since 1991.
20 Q. Now, in the clause that I
21 read to you, you talk about diverse
22 development and regulatory affairs
23 experience. What do you mean by the
24 development -- use of the word

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1 "development" in that clause?
2 A. While at -- my first
3 employment out of college was at
4 Burroughs Wellcome, which later became
5 GSK. I worked in quality as well as
6 chemical development for a number of
7 years.
8 Q. And in fact, your formal
9 education, at least so far as your CV
10 reflects, is that you possess both a BS
11 and a master's in chemistry; is that
12 correct?
13 A. That is correct.
14 Q. And you got your master's of
15 science in chemistry in 1989 is that
16 correct?
17 A. That's correct.
18 Q. And judging both by the fact
19 that you obtained it at East Carolina
20 University and the accent that I detect,
21 are you from the Carolinas or the south?
22 A. Yes, I am.
23 Q. Where do hail you from?
24 A. A little town called

<p>Page 26</p> <p>1 Princeton, which is like southeast of 2 Raleigh. 3 Q. Okay. And I gather when you 4 started out -- well, certainly at Mylan, 5 you moved a little further north, did you 6 not? 7 A. Yes. I moved from Raleigh 8 to Morgantown, West Virginia then. 9 Q. Now, in the summary of 10 your -- on your CV, you go onto say that 11 your experience was in new drug 12 development, generic drug development, 13 biological drug products, and consumer 14 health products. Is that correct? 15 A. That's correct. 16 Q. So -- 17 MR. TRISCHLER: Ruben, the 18 documents -- Ruben, the documents 19 just arrived. 20 So I was going to invite, 21 Mr. Talton, that you can look at 22 the document if you need to, to 23 respond to some of counsel's 24 questions.</p> <p>Page 27</p> <p>1 MR. HONIK: Sure. That's a 2 great idea. 3 BY MR. HONIK: 4 Q. And if you wouldn't mind 5 placing what we're going to mark 6 Talton-1, your CV, place that in front of 7 you, sir. 8 A. I got it. 9 Q. Very good. So just as a 10 point of orientation, in the summary it 11 says that you've got over 32 years of 12 experience. Is this the most current and 13 up-to-date CV for you? 14 A. It's the most recent one 15 that I've prepared. I haven't updated it 16 in a number of years. 17 Q. Okay. So but -- so that I'm 18 clear, is this the most up-to-date 19 currently available CV for you? 20 A. Yes. 21 Q. And did you prepare it in 22 its entirety? 23 A. Yes. 24 Q. Okay. And by that I mean,</p>	<p>Page 28</p> <p>1 did you have any assistance in preparing 2 any parts of it. I don't mean typing it, 3 but I mean the content. 4 A. No, I prepared it. 5 Q. Thank you. So before you 6 got the document in front of you now 7 marked Exhibit 1, we were talking about 8 your experience with new drug development 9 and generic drug development. 10 So that I have a working 11 definition of that, as you understand it, 12 what is new drug and generic drug 13 development as you define it? 14 A. New drug development is new 15 chemical entities or new therapies that 16 are not previously approved, where 17 generic drug development is a development 18 of a similar product as reference 19 product, as a generic drug. 20 Q. Understood. And the term or 21 word "development" in each of those 22 phrases, does that refer to the R&D and 23 the prelaunch regulatory matters that go 24 into the development and then</p> <p>Page 29</p> <p>1 commercialization of those drugs? 2 A. In general, yes. 3 Q. And we'll look at it in a 4 second or so. But it looks like you've 5 had experience in the chemistry lab side 6 as well as the regulatory affairs side in 7 connection with pharmaceutical 8 operations, correct? 9 A. Very early in my career, 10 yes. 11 Q. Okay. And we'll get to that 12 in a minute. But I gather in your job as 13 head of global regulatory affairs 14 presently you've become acquainted with 15 the process development side of the 16 regulatory scheme for introducing both 17 new and generic drugs, correct? 18 A. Could you clarify what you 19 mean by process development? 20 Q. Sure. Before either new 21 drugs or generic drugs launch 22 commercially, it's true, is it not, that 23 process chemists prepare processes that 24 go part and parcel into the filings with</p>
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<p>1 regulators; isn't that right?</p> <p>2 A. Yes. Drug applications,</p> <p>3 there's a description of how products are</p> <p>4 manufactured.</p> <p>5 Q. And those descriptions by</p> <p>6 process development professionals, also</p> <p>7 go into DMFs, do they not?</p> <p>8 A. There is a description of</p> <p>9 the manufacturing processes within a drug</p> <p>10 master file, yes.</p> <p>11 Q. And all I'm getting at, at</p> <p>12 this very preliminary stage, is that over</p> <p>13 the many years of your experience, you've</p> <p>14 come to understand the workings of how</p> <p>15 those professionals prepare submissions</p> <p>16 that you in turn use in the regulatory</p> <p>17 affairs department with filings with</p> <p>18 regulators; is that correct?</p> <p>19 A. Yes. I have a general</p> <p>20 understanding of what constitutes a drug</p> <p>21 application, what goes into them from a</p> <p>22 regulatory perspective.</p> <p>23 Q. And I gather in regulatory</p> <p>24 affairs that you collaborate with other</p>	<p>1 separate and sometimes distinct function</p> <p>2 in helping you to do your job as a</p> <p>3 regulatory affairs professional, correct?</p> <p>4 A. We rely upon a variety of</p> <p>5 functions in order to collect the</p> <p>6 necessary documents to compile a</p> <p>7 registration.</p> <p>8 Q. You indicate in your CV,</p> <p>9 marked Exhibit 1, that you are certified</p> <p>10 as a regulatory affairs -- or have a</p> <p>11 regulatory affairs certification; is that</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And apparently you obtained</p> <p>15 that in 1995; is that correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Have you been recertified</p> <p>18 since that year?</p> <p>19 A. It's -- it's a renewal, so</p> <p>20 every two to three years you have to get</p> <p>21 recertified.</p> <p>22 Q. Right. I understand.</p> <p>23 Excuse me. I didn't mean to speak over</p> <p>24 you.</p>
Page 31	Page 33
<p>1 units or divisions of your pharmaceutical</p> <p>2 company in order to comply with and</p> <p>3 create submissions for regulators,</p> <p>4 correct?</p> <p>5 A. There's multiple functions</p> <p>6 that provide source documents that go</p> <p>7 into a registration. So we do work with</p> <p>8 a variety of different functions to</p> <p>9 collect those source documents.</p> <p>10 Q. And can you identify the</p> <p>11 sources that you're referring to here</p> <p>12 that you collaborate with?</p> <p>13 A. Well, research and</p> <p>14 development, process development,</p> <p>15 quality, manufacturing operations, the</p> <p>16 legal department, labeling team, et</p> <p>17 cetera.</p> <p>18 Q. And I gather you've been</p> <p>19 collaborating with each of these areas or</p> <p>20 sections of the company in the many years</p> <p>21 that you've been a regulatory affairs</p> <p>22 professional, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And each of them serve a</p>	<p>1 A. The answer is yes, I</p> <p>2 maintain that certification.</p> <p>3 Q. So you have been recertified</p> <p>4 by RAC within the last three years?</p> <p>5 A. It's a continuous</p> <p>6 certification that you maintain.</p> <p>7 Q. It is my understanding --</p> <p>8 A. Can I explain?</p> <p>9 Q. Sure, you can.</p> <p>10 A. So the initial -- the</p> <p>11 original certification is based on</p> <p>12 completing a test -- test examination.</p> <p>13 And to maintain that certification, you</p> <p>14 have to continuously participate in</p> <p>15 conferences, meetings, to continue to</p> <p>16 earn points toward maintaining your</p> <p>17 certification. So you're not</p> <p>18 recertified. You simply maintain that</p> <p>19 through continuing education credits.</p> <p>20 Q. Okay. Now, according to</p> <p>21 this CV, sir, you are defined as the head</p> <p>22 of global regulatory affairs. Is that</p> <p>23 still your title and designation as a</p> <p>24 Viatrix employee?</p>

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1 A. Yes, at this time.
2 Q. What do you mean by "at this
3 time"? Is it about to change?
4 A. Well, we're undergoing
5 continuous reorganization right now. So
6 my current manager is head of global
7 regulatory affairs and product safety.
8 So there's no guarantee my title might
9 not evolve as we continue our
10 reorganization.
11 Q. Is your current, what you
12 define as manager, which straddles both
13 regulatory affairs and safety, an Upjohn
14 person or a Mylan person?
15 A. A legacy Mylan.
16 Q. And what's the name of that
17 manager?
18 A. Andrea Miller.
19 Q. And how long has she been
20 your manager straddling both regulatory
21 affairs and product safety?
22 A. She was named as part of the
23 Viatris introduction in November. But
24 she's been in and out of her regulatory

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1 roles over the years during my 20 years
2 at Mylan. So she's been my manager
3 previously.
4 Q. That's -- I may have asked
5 the question somewhat poorly. But prior
6 to merger or acquisition in late 2020,
7 was Ms. Miller a manager of yours for
8 some period of time?
9 A. Yes.
10 Q. And for how long prior to
11 2020 would that have been?
12 A. I would estimate maybe three
13 to four years. Because she was head of
14 regulatory affairs and research and
15 development.
16 Q. When did her role or title
17 shift to include product safety?
18 A. In November of 2020 when
19 Viatris was formed.
20 Q. I don't want to dwell
21 unnecessarily on this, but what does
22 product safety as a unit or division do
23 that's different, for example, from
24 regulatory affairs or R&D?

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1 A. Product safety and risk
2 management team, also known as PSRM, they
3 do adverse event reporting, so they do
4 case management, they prepare periodic
5 safety reports that go to the various
6 health authorities. And they're also key
7 in managing any risk management REMS
8 programs that we might have that are
9 approved as a condition for approval for
10 generic products.
11 Q. Understood. Who ran PSRM
12 for Mylan back before the merger or
13 acquisition in late '20?
14 A. Globally it's Balwant Heer.
15 And then we also have regional heads.
16 Q. And prior to November 2020,
17 were you a direct report to Ms. Miller?
18 A. Yes.
19 Q. And I gather you've been the
20 head of global regulatory affairs,
21 according to your CV, since 2016; is that
22 correct?
23 A. Yes.
24 Q. I want to understand some of

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1 the phrases that you employ in describing
2 your job as head of global regulatory
3 affairs.
4 In the first bullet there,
5 you indicate that you partner with
6 business to deliver new products and
7 maintain regulatory compliance. You've
8 spoken a bit about that. And you go on
9 to refer to established product
10 portfolio. What does that phrase mean?
11 A. The established product
12 portfolio, is that your question?
13 Q. That's my question, sir?
14 A. That's the approved products
15 or products that have already undergone
16 review and approval by a health
17 authority.
18 Q. Understood. The next and
19 final bullet refers to your strategic
20 leadership and comprehensive direction of
21 government regulatory requirements for
22 product introduction.
23 And I believe the
24 distinction that you're drawing there is

<p style="text-align: right;">Page 38</p> <p>1 that that would refer to products before 2 they become established portfolio 3 products, correct? 4 A. Yes. That covers both the 5 registration and approval. 6 Q. And just as a point of 7 reference for myself. Among the various 8 sources of collaboration that you 9 identified for me earlier, you'll 10 remember legal, labeling, R&D and the 11 like, which of those sources or divisions 12 or units do you collaborate with in 13 product introduction specifically? 14 A. We would interact with all 15 of those functions in order to compile a 16 registration to seek approval from a 17 health authority. 18 Q. Understood. 19 Then the next phrase that 20 you refer to in your description here is 21 commercialization. 22 Tell me the definition of 23 that, as you've used the word? 24 A. That just refers to, you</p>	<p style="text-align: right;">Page 40</p> <p>1 of those to make sure that we're 2 constantly, you know, continuing to 3 improve the quality of our applications 4 and meeting the health authority 5 expectation. 6 Q. You agree that that 7 requirement has been a presence in your 8 job the whole time that you've worked at 9 Mylan in regulatory affairs? 10 A. Yes. In order to be an 11 effective regulatory professional it's 12 important to know the requirements in 13 your various markets. 14 Q. You then go on to say, "and 15 create opportunities in a highly 16 regulated environment." 17 Unpacking that a bit. What 18 do you mean by create opportunities in 19 that phrase? 20 A. Supporting the business, 21 supporting the R&D, support the 22 registration of new products to help 23 bring those new products to market. 24 Q. Who has been the head of R&D</p>
<p style="text-align: right;">Page 39</p> <p>1 know, after obtaining the product 2 approval, providing support as necessary, 3 to support a launch of a product. 4 Q. Okay. 5 A. Commercialization. 6 Q. And would that include both 7 the launch and the actual sales functions 8 of getting it into the marketplace? 9 A. No. Regulatory works to 10 obtain the approvals, but once a product 11 is approved, we have no role in the 12 actual execution of launching a product 13 or selling our product. 14 Q. Understood. You go on to 15 refer to regulatory knowledge to ensure 16 compliance, which I understand, and 17 regulatory intelligence. 18 What does that phrase mean, 19 "regulatory intelligence"? 20 A. What I mean by that is we 21 closely monitor the change in regulatory 22 environment. When new guidances are 23 issued, new regulations come in place, 24 new requirements, we try to stay abreast</p>	<p style="text-align: right;">Page 41</p> <p>1 for the period of time that you've worked 2 at Mylan in regulatory affairs? 3 A. It's varied over my 20 years 4 at Mylan. It was Walt Owens for a while. 5 Andrea Miller held the role for a while. 6 Dan Snider was over R&D for a while. So 7 it's changed throughout my 20 years. But 8 those are the three most recent leaders. 9 Q. Again, I don't want to dwell 10 very long on it. Is R&D, is that 11 department sort of broken into the 12 different subdepartments or units that 13 perform different functions within R&D? 14 MR. TRISCHLER: Objection to 15 the extent that it's beyond the 16 scope of the designation. 17 You can answer to the extent 18 you know. 19 THE WITNESS: When I refer 20 to R&D, that would include 21 analytical sciences, process 22 development, you know, toxicology, 23 et cetera. 24 BY MR. HONIK:</p>

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1 Q. Thank you. I appreciate
2 that.
3 Is toxicology subsumed
4 within the R&D department or are they a
5 standalone department at Mylan during
6 your tenure?
7 A. It's a global -- it's a
8 global function.
9 Q. Okay. And then finally your
10 description here refers of course to the
11 highly regulated environment. What do
12 you understand the purpose of that highly
13 regulated environment? Why is it highly
14 regulated?
15 MR. TRISCHLER: Objection to
16 the form.
17 THE WITNESS: In order to
18 pursue the approval of a
19 pharmaceutical product in the U.S.
20 or any other market, there are
21 very specific requirements,
22 guidelines, regulations that --
23 that you have to follow in order
24 to do that. That's what I mean by

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1 highly regulated.
2 BY MR. HONIK:
3 Q. And do you know the
4 underlying purpose for the highly
5 regulated nature of the environment in
6 which you work?
7 A. It is to ensure that we meet
8 the standards of the requirements of the
9 various health authorities around the
10 globe.
11 Q. Okay. And do you have any
12 understanding of the reason why it's
13 highly regulated in order to meet or
14 satisfy the requirements of those
15 regulators? What is the underlying
16 purpose, if you understand it?
17 MR. TRISCHLER: Objection to
18 form.
19 THE WITNESS: There's
20 regulations and requirements that
21 you have to meet in order to
22 market these types of products.
23 So it is regulatory's role
24 to ensure that when we file the

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1 registration, that we are meeting
2 the expectations of those local
3 health authorities.
4 BY MR. HONIK:
5 Q. Let me ask the question this
6 way and then I'll move on. Do you have
7 any understanding that the environment is
8 highly regulated by the regulators with
9 which and with whom you interact day in
10 and week out and month out in order to
11 protect consumers who purchase and
12 consume the drugs that your company
13 makes?
14 MR. TRISCHLER: Objection to
15 form.
16 THE WITNESS: I mean, the
17 expectation that we produce
18 quality products that are -- that
19 are consumed by the general
20 public. It is a public health
21 role.
22 BY MR. HONIK:
23 Q. Okay. And do you,
24 therefore, understand that the underlying

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1 reason for having a highly regulated
2 environment in which you operate is at
3 the end of the day, to protect those
4 consumers to whom you sell drugs?
5 MR. TRISCHLER: Objection to
6 form.
7 Objection. Asked and
8 answered.
9 THE WITNESS: To ensure the
10 quality of the products that we
11 produce in accordance with how
12 they are approved by the local
13 health authorities based on the
14 various requirements across the
15 globe.
16 BY MR. HONIK:
17 Q. You then describe the job
18 that you held from 2014 to 2016 on your
19 CV as head of global regulatory science
20 and operations.
21 Do you see that?
22 A. Yes.
23 Q. Can you first tell me the
24 difference between global regulatory

<p style="text-align: right;">Page 46</p> <p>1 affairs and global regulatory science and 2 operations?</p> <p>3 A. Yeah. So global regulatory 4 affairs is more of the overarching role, 5 which includes regulatory science, 6 regional regulatory teams and operations, 7 which is the mechanics of which we 8 execute, publish, produce submissions. 9 During 2014 to 2016, my role 10 was not the overarching global head. But 11 more specific on the reg science teams, 12 the teams that prepare generic drug 13 submissions, and operations which is the 14 team that actually prepares our 15 electronic submissions and archives and 16 publishes and transmits those.</p> <p>17 Q. Is it fair to say that 18 global regulatory science and operations 19 is subsumed structurally within global 20 regulatory affairs?</p> <p>21 A. Yes. Those are subfunctions 22 within global regulatory affairs.</p> <p>23 Q. And can you identify other 24 sub functions that you supervise or</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. So are regional reg teams 2 related more to geography than any 3 specific subfunction?</p> <p>4 A. They are broken down by the 5 markets that they support. So they are 6 regionally located. But their role is to 7 support registrations in those specific 8 markets.</p> <p>9 Q. Understood. And as head of 10 global reg affairs, do you oversee all of 11 the regional reg teams?</p> <p>12 A. Currently, yes.</p> <p>13 Q. And that's been the case 14 since 2016?</p> <p>15 A. Yes.</p> <p>16 Q. And does that function 17 require you to familiarize yourself with 18 the various regulatory structures and 19 architecture of the different regions in 20 which Mylan sells drugs?</p> <p>21 A. Only at a very high level. 22 I have very strong regional and country 23 managers, and I rely upon them to 24 understand their market and run those --</p>
<p style="text-align: right;">Page 47</p> <p>1 oversee as global regulatory affairs 2 head?</p> <p>3 A. We also have a regulatory 4 policy team, which gets back to sort of 5 the regulatory intelligence area. We 6 have a team that monitors the regulatory 7 environments to ensure that we're 8 monitoring that and continuously meeting 9 the new expectation.</p> <p>10 Q. Okay. So if I've noted them 11 correctly, I know that you identified 12 regulation or reg policy, which relates 13 to intelligence.</p> <p>14 You've identified and 15 defined reg science and operations or 16 operating -- operations.</p> <p>17 Are there any other, as you 18 called it, subfunctions within regulatory 19 affairs that you supervise or oversee?</p> <p>20 A. The other major group would 21 be our regional regulatory team. So 22 based on -- we have a European regulatory 23 affairs team, emerging markets, Japan, 24 Australia, and New Zealand.</p>	<p style="text-align: right;">Page 49</p> <p>1 those regional teams.</p> <p>2 Q. Sure. But from a management 3 standpoint, you're nonetheless the head 4 structurally over these various regional 5 reg teams, correct?</p> <p>6 A. I am the people manager. 7 But I expect my leaders to understand 8 their markets and run their businesses 9 locally.</p> <p>10 Q. Understood. And part of how 11 that happens is that your regional reg 12 teams, in the various geographic markets 13 that you serve and are regulated by 14 become acquainted with the regulatory 15 schemes, rules, and regulations of the 16 respective markets that they operate in, 17 correct?</p> <p>18 A. The regional leaders, that's 19 their role is to understand the local and 20 regional markets. So I rely upon them to 21 do that.</p> <p>22 Q. I understand. And let me 23 ask it this way, and I'll move on. By 24 way of example, you've got a regional reg</p>

<p>Page 50</p> <p>1 team that operates in Europe and is 2 regulated by EMEA, correct? 3 A. Yes. And various local 4 country health authorities. 5 Q. Correct. And I gather from 6 your previous answers, that those 7 managers who are people that you in turn 8 manage, they're the ones that have to 9 become intimately acquainted with the 10 regulatory schemes of those various 11 countries or European market in order to 12 discharge their functions, correct? 13 A. I would consider them the 14 local subject matter experts in those 15 markets, yes. 16 Q. And do you consider yourself 17 a local market expert in U.S. FDA 18 regulatory scheme? 19 MR. TRISCHLER: Objection to 20 the form. 21 THE WITNESS: I have been 22 working in the U.S. regulatory 23 environment pretty much my entire 24 career. So I do have my years of</p> <p>Page 51</p> <p>1 experience in this market. 2 BY MR. HONIK: 3 Q. Okay. And it's not unfair 4 to say that you are an expert in FDA 5 regulation, correct? 6 MR. TRISCHLER: Objection to 7 the form. 8 THE WITNESS: I mean, I feel 9 like I'm somewhat familiar with 10 the requirements in the U.S. 11 I mean, whether or not I'd 12 call myself an expert is 13 debatable. 14 BY MR. HONIK: 15 Q. At one point you served as 16 vice president -- it's actually listed 17 forward slash head of global regulatory 18 affairs/operations at Mylan. That was 19 from 2009 to '14. 20 Tell me about that job and 21 how it differed from the two we've 22 already looked at. 23 A. In that role it was very 24 specific to operations, which is the</p>	<p>Page 52</p> <p>1 function I described previously. It's 2 the team that prepares submissions, 3 publishes submissions, transmits those, 4 more the executional function in 5 regulatory affairs. 6 Q. Okay. And in that job, you 7 were based in Morgantown as well? 8 A. Yes. 9 Q. In describing that 10 particular job from 2009 to '14, you 11 write that you partnered closely with R&D 12 development teams to develop and prepare 13 high quality submissions for worldwide 14 registration. Do you see that sentence? 15 A. Yes. 16 Q. We've talked a tiny bit 17 about this. But can you be more specific 18 in telling me the way in which you 19 partner closely with R&D development 20 teams? 21 A. When preparing a new drug 22 submission that requires multiple 23 component-type documents, we worked very 24 closely with the research and development</p> <p>Page 53</p> <p>1 team that did the development work for 2 the product to obtain those source 3 documents to support the registration. 4 Q. And I apologize in advance 5 if I use the wrong phrases, because 6 you're the professional in reg affairs, 7 and not me. 8 But is it the R&D 9 development teams that basically create 10 the molecule that goes on to become the 11 subject of a submission and hopefully 12 approval by the regulatory agency? 13 A. I wouldn't use the term 14 "create the molecule." Our primary 15 business generally was drug generic 16 development. So the molecule was already 17 established. 18 Q. Right. 19 A. But R&D would manage the 20 development of a formulation that we 21 could register as a generic. 22 Q. And that would lead to the 23 preparation and submission of an 24 abbreviated new drug application in order</p>
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1 to get approvals, correct?

2 A. In the U.S., yes.

3 Q. Right. And unless I

4 indicate otherwise, I'm referring

5 specifically to the U.S. FDA.

6 So by way of a follow-up

7 question, would an example of a close

8 partnering or collaboration with R&D in

9 the development for a submission, might

10 an example of that be processes that the

11 R&D team prepares that are then relied

12 upon by reg affairs in submitting the

13 application? Is that an example?

14 A. As I previously testified, a

15 dossier or registration is a compilation

16 of a variety of documents that are

17 required. And regulatory affairs, we

18 source those documents from the various

19 functions that are responsible for

20 preparing the documentation, which would

21 include, you know, development-type

22 documents.

23 Q. And just, this is as much

24 for my own edification as anything. Is

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1 an example of that a development team's

2 setting out the process by which a

3 generic drug is manufactured?

4 A. A description of the

5 manufacturing process for an active

6 ingredient and a finished dosage form are

7 included in a drug registration.

8 Q. And I gather over the many

9 years that you've supervised that work

10 specifically and now as head of global

11 reg affairs, you've certainly seen many

12 examples of that, and you're familiar

13 with submissions of that sort, right?

14 A. I don't supervise that

15 function.

16 As I mentioned previously,

17 in regulatory affairs, we're not

18 responsible for those documents. We

19 collect those source documents from the

20 various functions and compile them into a

21 dossier.

22 You indicated that I would

23 manage that function, and that's not the

24 case.

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1 Q. I take the distinction.

2 So in reg affairs,

3 particularly as the head, and in

4 management, you collect those source

5 documents and then employ them as

6 appropriate in the submission; is that

7 fair?

8 A. We collect them from the

9 various departments who are responsible

10 for those documents. And we put them

11 into the submission to meet the local

12 health authority requirement.

13 Q. Okay. And we may have

14 occasion to get into this in some detail

15 later. But at a high level, when you

16 collect those documents as part of the

17 dossier and prepare for submission, to

18 what extent, if any, does regulatory

19 affairs edit or change the content of the

20 submissions that you collect from these

21 other units?

22 A. We rely upon those teams to

23 provide us current documentation that

24 meets the local health authority

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1 requirement. So those, is really more of

2 a compilation, making sure that it meets

3 the local health authority requirements

4 and that they are formatted properly for

5 the registration.

6 Q. Okay.

7 A. We rely upon the scientists

8 who are preparing those documents to

9 provide those to regulatory in complete

10 form.

11 Q. So is that another way of

12 saying in more plain language that you

13 don't change the science in regulatory

14 affairs; you're really collecting and

15 compiling it and ensuring that it meets

16 the format in which you're required to

17 submit it. Is that fair?

18 A. I would describe it as

19 regulatory is more of custodians. So our

20 job is to compile the dossier. And we

21 work with those teams to collect the

22 necessary documents. But we're not

23 responsible for the science in those

24 documents.

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1 Q. And by turn, that means that
2 you don't change the science when you get
3 it from those teams, correct?
4 A. We rely upon those teams to
5 provide us with complete, well supported
6 science documents.
7 Q. What does the phrase -- or
8 phrase, yeah -- route of synthesis for a
9 molecule mean to you?
10 MR. TRISCHLER: Objection to
11 the form and foundation.
12 THE WITNESS: Route of
13 synthesis to me means the
14 description of the manufacturing
15 process by which an active
16 pharmaceutical ingredient is
17 manufactured.
18 BY MR. HONIK:
19 Q. And that comports with my
20 own understanding. Thank you.
21 Do you rely in regulatory
22 affairs on one or more of the R&D
23 development teams to give you a
24 description of a route of synthesis for a

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1 molecule to assist you in your submission
2 to the regulator?
3 A. Not directly from R&D. In
4 most cases for generic drug application,
5 we refer to a drug master file. So as an
6 applicant for a generic drug product we
7 don't have access to those details.
8 Q. Let me unpack that a little
9 bit. When you say that you don't have
10 access to those details, what do you mean
11 and what don't you have access to?
12 A. A drug master file describes
13 how an active pharmaceutical ingredient
14 is manufactured. That is typically
15 maintained or put into what we call drug
16 master file in the U.S. That's a
17 confidential document. As an applicant
18 for a generic drug product, we would
19 obtain a letter of authorization from
20 that DMF holder to allow FDA to review
21 that confidential information on our
22 behalf.
23 But as an applicant, we
24 don't -- we don't have access to the full

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1 drug master file.
2 Q. Okay. And as -- are you
3 presupposing in the case of valsartan,
4 that Mylan didn't create the DMF for
5 valsartan?
6 A. In the case of valsartan,
7 the drug master file is held by Mylan
8 Laboratories Limited which is a
9 subsidiary of Mylan.
10 Q. And what's your familiarity
11 with the DMF application submitted by
12 Mylan for valsartan?
13 A. I'm sorry. Could you repeat
14 that?
15 Q. Sure. Was Mylan an
16 applicant in submitting a DMF to the U.S.
17 FDA for valsartan?
18 A. Mylan Laboratories Limited,
19 yes.
20 Q. And are you familiar with
21 MLL's preparation for and submission of
22 the DMF to the U.S. FDA?
23 A. Yes. I am aware that they
24 prepared a drug master file and they

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1 provided us a letter of reference, a
2 letter of authorization to that drug
3 master file as the applicant for
4 valsartan tablets.
5 Q. And were you -- at the time
6 that occurred, what was your role at
7 Mylan? I know you were there.
8 A. I don't recall when the drug
9 master file was actually submitted. I
10 would have to go back and look at the
11 date that the DMF was filed to match it
12 up to what position I had at that time.
13 I don't recall.
14 Q. Fair enough. Regardless of
15 your position at the time -- and that's
16 not consequential right at this very
17 moment -- what do you remember your role,
18 if any, being at the time in the
19 submission of that DMF application?
20 A. I was most likely in my
21 North America role or my global role for
22 overseeing the various regional teams as
23 we described previously.
24 Q. And so can you give me a

<p>Page 62</p> <p>1 kind of high level description of the 2 various moving parts at Mylan? And by 3 that I refer to all the entities that may 4 have been involved in the submission of 5 that DMF.</p> <p>6 How did the presubmission 7 and then the actual submission take 8 place? Tell me the parts that came 9 together to be able to do that.</p> <p>10 A. Well, we've already talked 11 about two sort of separate submissions. 12 There's the drug master file submission 13 that describes the method of manufacture 14 for a specific active pharmaceutical 15 ingredient.</p> <p>16 In the case of valsartan, 17 that was prepared by Mylan Laboratories 18 Limited in India.</p> <p>19 As applicant for Mylan 20 Pharm's filed ANDA -- excuse me -- for 21 valsartan tablets, we obtained a letter 22 of authorization to that drug master file 23 to put into our ANDA.</p> <p>24 In other words, we don't</p> <p>Page 63</p> <p>1 include the details of that DMF in our 2 ANDA because we rely upon the 3 confidential DMF document to support 4 that.</p> <p>5 Q. Okay. I understand that. 6 Let's break those up for a moment and let 7 me ask some more detailed questions. I 8 want to focus on the DMF part of what you 9 just said to me.</p> <p>10 And you indicated that, of 11 course, that submission was by MLL. And 12 it describes the method of manufacturing, 13 in this case, the API, correct?</p> <p>14 A. Yes. The drug master file.</p> <p>15 Q. And tell me, if you could, 16 in some detail, it will be helpful for me 17 going forward for you today -- with you 18 today, the various parts of Mylan's 19 organizations, in any of its units, in 20 any of its subsidiaries or divisions that 21 come together to collaborate in order to 22 submit that DMF?</p> <p>23 A. The way you've asked that 24 question, it's difficult to answer.</p>	<p>Page 64</p> <p>1 But generally the drug 2 master file team is a separate business 3 unit, per se. So there's an API business 4 that was part of Matrix, which Mylan 5 obtained in mid 2000s.</p> <p>6 So that's an API business 7 where they hold a variety of drug master 8 files that are made available to products 9 that might be pursued by Mylan. They 10 also supply APIs to other -- other third 11 parties that may also be registering 12 products throughout the world.</p> <p>13 Q. Okay. I totally understand 14 that. I understand there's an API team. 15 And I understand that there was an 16 acquisition of an entity called Matrix in 17 the mid 2000s.</p> <p>18 But you were, I think, 19 telling me the various teams that may 20 have roles in preparing and then 21 submitting the DMF, in this case on 22 behalf of MLL.</p> <p>23 Apart from the API team, 24 which you've described to me and their</p> <p>Page 65</p> <p>1 function, what other teams or units at 2 any entity in Mylan participates in the 3 preparation of that DMF for submission?</p> <p>4 A. It's primarily managed 5 within that API science team as a 6 deliverable. But because the -- because 7 the facility is a foreign-located 8 facility, we are required in the U.S. to 9 have a U.S. agent. So in other words, 10 someone that can liaise with FDA on their 11 behalf.</p> <p>12 Q. And do you recall who that 13 U.S. agent was in the case of the DMF 14 submission by MLL for valsartan?</p> <p>15 A. I don't know if it changed 16 over time. Our current U.S. agent is 17 Michael Plastina. Before that, they 18 had -- they had a third party doing their 19 drug -- their U.S. agent work.</p> <p>20 Q. They do that? Thank you. 21 That --</p> <p>22 A. I don't recall who that was.</p> <p>23 Q. That's helpful. 24 And what is the role from a</p>
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<p>Page 66</p> <p>1 regulatory affairs or legal standpoint of 2 that U.S. agent? In what way are they 3 liaising? 4 A. It's really just a conduit, 5 you know, to the local health authority. 6 A U.S. agent is required 7 just to facilitate communications, 8 written communications, telephone calls, 9 on the same time zone. But that U.S. 10 agent relies entirely upon the DMF holder 11 for the DMF content and the science 12 behind that. 13 Q. Now, you did refer to the 14 API team that used to be Matrix, it was 15 acquired by Mylan, as a science team, did 16 you not? 17 A. I did just because it fits 18 into what we call regulatory science 19 teams, which we talked about previously. 20 Q. Okay. And by that, in the 21 case of this API science team and the DMF 22 submission for valsartan, those would be 23 the science or R&D professionals that, 24 among other things, would lay out the</p> <p>Page 67</p> <p>1 method and manufacturing process for the 2 API, correct? 3 A. That came with a 4 responsibility for preparing the 5 documentation and doing the work to 6 support the preparation of a drug master 7 file. 8 Q. And in that submission or in 9 those documents would be a description of 10 the manufacturing process, correct? 11 A. That is included in the drug 12 master file, yes. 13 Q. And is the route of 14 synthesis also described in those 15 documents? 16 A. Yes. 17 Q. And if I've now understood 18 the structure, your role in regulatory 19 affairs is -- and I'm not minimizing 20 it -- is to collect their work product 21 and format it into your submission, in 22 this case for the DMF, correct? 23 A. Yes, in general. Again, 24 we're sort of a custodian. We don't own</p>	<p>Page 68</p> <p>1 the science. We don't own the 2 documentation. But we help to manage it 3 and make sure that we present it properly 4 in the various markets based on what 5 those requirements might be. 6 Q. Wait. Let me unpack that a 7 little bit, because when you say that you 8 don't own it, does that imply that you 9 don't change the science? You just 10 ensure that it's formatted in an 11 appropriate way given the demands of the 12 regulatory scheme? 13 A. Yeah, regulatory affairs do 14 not change the science. We rely upon the 15 scientists to provide us with completed 16 documentation. So the answer to your 17 question is no, regulatory affairs 18 doesn't change the science. 19 Q. And does that imply as well 20 that you don't change the scientific 21 description of the manufacturing process? 22 A. That's correct. That's a 23 deliverable that comes to us based on our 24 market. Regulatory affairs doesn't</p> <p>Page 69</p> <p>1 change that. We rely upon that. 2 Q. Thank you. I appreciate 3 your answer. 4 Between 2007 and 2009 you 5 apparently served as vice president for 6 regulatory affairs or North America. 7 Do you see that? 8 A. Yeah. 9 Q. And in the first bullet, you 10 say that you oversaw the day-to-day 11 operations. 12 How is that oversight 13 different than the kind of head 14 responsibilities that you currently have? 15 A. That role was specifically 16 for North America, which was U.S. and 17 Canada. 18 Q. Okay. 19 A. So not a global role, but a 20 regional role. 21 Q. Okay. And apart from the 22 geographic difference, should I take any 23 particular meaning to your description of 24 oversight as being on a day-to-day</p>
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1 operational basis? Is that different
2 than your current responsibility?
3 A. I mean, generally it's the
4 same sort of activity, but it was more
5 localized versus global. A much smaller
6 number of people, smaller portfolio. It
7 was limited to what was happening in
8 North America, not across the globe.
9 Q. I totally get that.
10 So would it be fair to say
11 that your current job involves oversight
12 of the day-to-day operations of
13 regulatory affairs globally?
14 A. Yes, in general. But as I
15 testified previously, I have very strong
16 leaders across the globe that I rely upon
17 them to manage their local day-to-day
18 teams and operations. I'm a people
19 manager when it gets to outside the U.S.
20 Q. Totally understand your
21 answer. Thank you.
22 Now, and I think we've
23 discussed this, but you started at Mylan
24 in 2001, correct?

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1 A. Yeah.
2 Q. And prior to that, you had
3 similar regulatory affairs positions at
4 GSK. And before that I guess when it was
5 Burroughs Wellcome, correct?
6 A. Yes. I had a variety of
7 roles while -- during my tenure at GSK.
8 Q. I see for a short period of
9 time you were a consultant of some sort
10 with an entity called ClinTrials Research
11 Inc.?
12 A. That's correct.
13 Q. What is that entity and what
14 did you do for that?
15 A. ClinTrials Research Inc. was
16 a clinical research organization. So I
17 was providing regulatory consulting
18 essentially for persons interested in
19 registering products in the U.S.
20 Q. And where were they located,
21 where were you located at that time?
22 A. Resource Triangle Park in
23 North Carolina.
24 Q. Your job -- is it pronounced

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1 Parexel? Am I pronouncing that
2 correctly?
3 A. Parexel.
4 Q. Parexel in worldwide
5 regulatory affairs as a senior
6 consultant. Is that -- was that somewhat
7 a more junior job in regulatory affairs,
8 similar nonetheless, to the one that you
9 hold now?
10 A. It wasn't the same level
11 responsibility. Again, it was similar to
12 my work at ClinTrials. Parexel was also
13 a clinical research organization. So
14 companies would hire them to help them
15 make registration. So I provided
16 regulatory consulting services based on
17 my experience.
18 Q. Understood. Among the
19 descriptors of that position, you say
20 that you conduct current good
21 manufacturing practices audits.
22 Do you see that?
23 A. Yes.
24 Q. So I take it that you became

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1 acquainted with cGMP requirements and
2 guidelines in discharging that job
3 function, correct?
4 A. I was aware at that time of
5 the current practices and I participated
6 in a couple of audits, but I would not
7 consider myself an expert in that area.
8 Q. Fair enough. From '98
9 forward, what was the extent of your
10 involvement with cGMP?
11 A. None really.
12 Q. Did you maintain or continue
13 to maintain at Mylan at least some level
14 of familiarity, if not expertise, in cGMP
15 and how it interacts or interfaces with
16 regulatory affairs?
17 MR. TRISCHLER: Objection to
18 the form.
19 THE WITNESS: When you're
20 referring to cGMPs, you're talking
21 about operations locally at our
22 facilities establishments.
23 Regulatory affairs relies upon
24 other teams to manage those

<p style="text-align: right;">Page 74</p> <p>1 day-to-day operations. 2 In the case of Mylan and 3 Viatris, we rely upon quality to 4 oversee that area. 5 BY MR. HONIK: 6 Q. Do you in reg affairs, 7 nonetheless collaborate with the quality 8 area as it concerns cGMP? 9 A. They may consult with us, if 10 something comes up during an audit that 11 has an overlay with regulatory affairs. 12 But in general, quality 13 managers, manage the compliance at their 14 site without regulatory intervention. 15 Q. Understood. And then at 16 some point before you got into regulatory 17 affairs, you worked as a chemist or a 18 scientist, correct? 19 A. Yes. When I first entered 20 the industry, I was in a science role. 21 Q. And if I'm looking at this 22 correctly, you did that actually while 23 you were still in college and graduate 24 school, correct?</p>	<p style="text-align: right;">Page 76</p> <p>1 regulatory affairs professional from the 2 relevant teams at Mylan, correct? 3 A. Yeah, we obtained anything 4 dealing with the development or the 5 method of manufacture for an API, we 6 obtain that source documentation from 7 those functions that are responsible for 8 us. 9 Q. Correct. And all I'm doing 10 is underscoring the fact that presently 11 as head of regulatory affairs, that's 12 among the deliverables that you collect, 13 that's what you've told me, to help 14 regulatory affairs prepare submissions to 15 the FDA among others, correct? 16 A. That's correct. 17 Q. And all I'm getting at is 18 back in '85 to '91, you were on the other 19 side of that, helping to collect 20 scientifically the processes and the 21 other data necessary to support, among 22 others, the regulatory affairs function 23 of submitting applications, correct? 24 A. In that specific role, yes,</p>
<p style="text-align: right;">Page 75</p> <p>1 A. Yes. I started my first job 2 after obtaining my bachelor's degree and 3 I pursued my master's while working 4 full-time. 5 Q. That was what was then 6 Burroughs Wellcome, correct? 7 A. That's correct. 8 Q. And for well over six years, 9 you were in something called the chemical 10 development lab there, correct? 11 A. Yes. 12 Q. And your job was as a 13 development scientist, correct? 14 A. That was my job title, yes. 15 Q. And among the things that 16 you described doing was developed 17 chemical processes for transfer from 18 laboratory scale to production scale. 19 Correct? 20 A. Yes. That was the role that 21 I was in. 22 Q. And that type of work is now 23 work that, if I've understood you 24 correctly, you now compile as a</p>	<p style="text-align: right;">Page 77</p> <p>1 that was to facilitate the scale up of 2 processes, API processes from a lab scale 3 to a production scale. 4 Q. Okay. And all I'm getting 5 at, sir, is that you've now had 6 experience in your professional life on 7 both sides of that equation, that is to 8 say, the science which is now a 9 collectable to you as a regulatory 10 affairs professional at Mylan, correct? 11 A. I mean. 12 MR. TRISCHLER: Objection to 13 form. 14 THE WITNESS: I have worked 15 in both quality and development, 16 and regulatory affairs was part of 17 my career. 18 But you know, I think this 19 was very important to note that 20 this was very early in my career. 21 It's been a long time since I've 22 been directly involved with 23 bench-type science. 24 BY MR. HONIK:</p>

<p style="text-align: right;">Page 78</p> <p>1 Q. I promise you today that I</p> <p>2 will not ask you any bench-type questions</p> <p>3 about chemistry. Okay?</p> <p>4 A. Okay.</p> <p>5 Q. Sir, you understand that</p> <p>6 you're here today to give testimony under</p> <p>7 oath as a representative of Mylan in</p> <p>8 certain areas, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And have you had occasion</p> <p>11 before today to review the topics about</p> <p>12 which I'm going to question you today?</p> <p>13 A. Yeah.</p> <p>14 Q. And generally speaking, you</p> <p>15 understand, do you not, that I'm going to</p> <p>16 question you about communications Mylan</p> <p>17 had with its regulators full stop,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you understand that I'm</p> <p>21 going to question you about Mylan's</p> <p>22 filings with regulatory authorities</p> <p>23 including the FDA, all of which is</p> <p>24 concerning valsartan API, correct?</p>	<p style="text-align: right;">Page 80</p> <p>1 designated on the breadth of the</p> <p>2 scope as represented by counsel.</p> <p>3 But you can answer what</p> <p>4 you've done.</p> <p>5 THE WITNESS: Obviously as</p> <p>6 I've described to you today, my</p> <p>7 role in regulatory affairs. Those</p> <p>8 sort of communications were not my</p> <p>9 day-to-day responsibilities.</p> <p>10 But in preparation for</p> <p>11 today, I have familiarized myself</p> <p>12 with -- with the -- with those</p> <p>13 communications so that I could</p> <p>14 testify today.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. I understand. And you have</p> <p>17 been designated by the company on those</p> <p>18 topics.</p> <p>19 My question to you, sir, is</p> <p>20 what did you do to prepare to answer</p> <p>21 questions in that area? What documents</p> <p>22 did you look at? What did you do?</p> <p>23 A. I met with both internal and</p> <p>24 external counsel here on a few occasions.</p>
<p style="text-align: right;">Page 79</p> <p>1 A. Yes.</p> <p>2 Q. Do you understand as well,</p> <p>3 that you're going to be questioned today</p> <p>4 under oath about Mylan's communications</p> <p>5 with finished dose customers and</p> <p>6 downstream customers?</p> <p>7 MR. TRISCHLER: Objection to</p> <p>8 form.</p> <p>9 BY MR. HONIK:</p> <p>10 Q. You can answer.</p> <p>11 A. Yes. I understand that was</p> <p>12 one of the topics.</p> <p>13 Q. All right. So let's take</p> <p>14 them in reverse order. Again, I don't</p> <p>15 want to dwell on this, but I do want to</p> <p>16 have a framework understanding from you,</p> <p>17 sir.</p> <p>18 What did you do to prepare</p> <p>19 the area that I'm going to question you</p> <p>20 about concerning Mylan's communications</p> <p>21 with finished dose customers and</p> <p>22 downstream customers?</p> <p>23 MR. TRISCHLER: Objection to</p> <p>24 the form. The witness hasn't been</p>	<p style="text-align: right;">Page 81</p> <p>1 Also reviewed documentation in</p> <p>2 preparation for today's deposition.</p> <p>3 And spoke to the person</p> <p>4 responsible for, you know, overseeing the</p> <p>5 recalls within the Mylan quality network.</p> <p>6 Q. Who oversaw the recall for</p> <p>7 Mylan?</p> <p>8 A. I spoke to Deva. I'm sorry.</p> <p>9 I forget his last name. I forget his</p> <p>10 last name.</p> <p>11 Q. Okay. When did you speak to</p> <p>12 Deva?</p> <p>13 A. Yesterday.</p> <p>14 Q. Was that the only occasion</p> <p>15 that you spoke to Deva?</p> <p>16 A. Yes.</p> <p>17 Q. What is Deva's title or role</p> <p>18 at the company?</p> <p>19 A. I don't know that without</p> <p>20 looking it up, sorry.</p> <p>21 Q. Okay. Where is Deva based?</p> <p>22 A. He was in India, when we</p> <p>23 spoke with him yesterday.</p> <p>24 Q. When you say we, who</p>

<p>Page 82</p> <p>1 participated in the conversation?</p> <p>2 A. Counsel that's represented</p> <p>3 here today.</p> <p>4 Q. Okay. I don't want to know</p> <p>5 what they said to you and you said to</p> <p>6 them. But what did you learn from Deva?</p> <p>7 A. Since this was an area that</p> <p>8 was outside of my day-to-day activities,</p> <p>9 he described the overall framework for</p> <p>10 recalls, how -- how the process works and</p> <p>11 who they would have communicated with.</p> <p>12 Q. Okay. And you mentioned</p> <p>13 having reviewed documents in connection</p> <p>14 with these topic areas. As a Mylan</p> <p>15 designee, what did you look at?</p> <p>16 A. Specifically the recall</p> <p>17 notices that indicate the valsartan</p> <p>18 tablets.</p> <p>19 Q. Okay. Anything other than</p> <p>20 the recall notices?</p> <p>21 A. Not for this topic, no.</p> <p>22 Q. But I gather from your</p> <p>23 answer that you looked at other documents</p> <p>24 concerning the other topics; is that</p>	<p>Page 84</p> <p>1 Q. So stated otherwise, there's</p> <p>2 no document that you used to prepare for</p> <p>3 your testimony as a designee today that</p> <p>4 wasn't provided to you directly by</p> <p>5 counsel, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. So we've talked a little bit</p> <p>8 about the documents that you looked at in</p> <p>9 connection with the recall areas of</p> <p>10 testimony.</p> <p>11 Tell me, in terms of the</p> <p>12 communication with regulators, and</p> <p>13 filings and the like, what documents you</p> <p>14 looked at categorically.</p> <p>15 A. Could you repeat that? Are</p> <p>16 you talking about health authority</p> <p>17 communications specifically?</p> <p>18 Q. I'm happy to clear it up.</p> <p>19 What categories of documents</p> <p>20 did you look at in connection with the</p> <p>21 areas of testimony that you're here to</p> <p>22 give in terms of communication with</p> <p>23 regulators and filings?</p> <p>24 A. It was primarily</p>
<p>Page 83</p> <p>1 correct?</p> <p>2 A. Yes. I looked at other</p> <p>3 documents including health authority</p> <p>4 communications.</p> <p>5 Q. And how were those documents</p> <p>6 compiled? Is that something that you</p> <p>7 undertook to look for, secure, and</p> <p>8 review? Or were they provided to you or</p> <p>9 both?</p> <p>10 A. They were provided to me.</p> <p>11 Q. Would that be true in every</p> <p>12 instance? That is to say, every document</p> <p>13 that you looked at in preparation for</p> <p>14 your designated testimony today was</p> <p>15 provided to you by counsel; is that</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And just before moving on,</p> <p>19 as a result of looking at any of those</p> <p>20 documents, did you undertake any search</p> <p>21 of additional documents on your own to</p> <p>22 further prepare you or enlighten you for</p> <p>23 your testimony?</p> <p>24 A. No, I did not.</p>	<p>Page 85</p> <p>1 communications to and from the various</p> <p>2 health authorities. So information</p> <p>3 requests, our responses to those, et</p> <p>4 cetera.</p> <p>5 Q. When you say health</p> <p>6 authorities, you mean the U.S. FDA, as</p> <p>7 well as their counterparts globally?</p> <p>8 A. Yes. I focused primarily on</p> <p>9 the U.S., which seemed to be the most</p> <p>10 relevant, but I'm somewhat familiar with</p> <p>11 other communications that may have</p> <p>12 occurred.</p> <p>13 Q. Okay. And to that end you</p> <p>14 looked at documents that were to or from</p> <p>15 Mylan entities and foreign health</p> <p>16 authorities, correct?</p> <p>17 A. Those were among some of the</p> <p>18 documents that I looked at.</p> <p>19 Q. Are there any other</p> <p>20 categories of documents on any other</p> <p>21 topics that you've been designated on</p> <p>22 that you've looked at that you haven't</p> <p>23 already told me about?</p> <p>24 A. No.</p>

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1 Q. It may be useful -- hold on.
2 I'm having a little tech problem.
3 It may be useful for you and
4 I to have some basic understanding as we
5 move through my questioning today about
6 the understanding that Mylan eventually
7 had about the root cause presence of NDEA
8 and NDMA in its valsartan product.
9 The question that I have for
10 you is, do you have some understanding of
11 what the root cause was?
12 MR. TRISCHLER: Objection to
13 the extent that it's beyond the
14 scope.
15 You can answer to the extent
16 that you have personal knowledge.
17 THE WITNESS: I recall
18 seeing some documentation that
19 talked about -- that identified
20 the potential root cause.
21 BY MR. HONIK:
22 Q. And what was the root cause
23 that you saw?
24 A. Following the investigation,

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1 there was a conclusion that there may
2 have been some carryover of impurities in
3 one of the recovered solvents that was
4 used in the API synthesis.
5 Q. And you know more
6 particularly in what way the use of
7 recovered solvent produced the
8 carryover -- what you described as the
9 carryover impurity?
10 MR. TRISCHLER: Same
11 objection to the extent that it's
12 beyond the scope.
13 THE WITNESS: I don't have
14 that detailed level of knowledge.
15 All I know is, you know, what was
16 referred to in the documentation.
17 BY MR. HONIK:
18 Q. And what did you look at
19 that revealed to you this knowledge about
20 the root cause?
21 A. As I previously testified,
22 it was described within communications
23 that were made to health authorities
24 following --

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1 Q. Of this -- I'm sorry. I
2 spoke over you. What did you say?
3 A. I was just saying following
4 the investigation that was disclosed to
5 health authorities in response to their
6 queries.
7 Q. So you're referring to
8 communications between Mylan in
9 describing root cause to health
10 authorities; is that correct?
11 A. Yes.
12 Q. And as a chemist, and as
13 someone who has worked in the various
14 areas including regulatory affairs, as
15 you've now described to me, did you
16 understand in anymore detail how the
17 presence of the carryover impurities got
18 where they got?
19 A. No, I'm not familiar by the
20 process of which solvents were recovered.
21 So I'm not going to be able to comment on
22 details around that.
23 Q. Well, in the course of
24 preparing for your testimony as a

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1 designee, did you see any documents or
2 review any documents that revealed the
3 recovery process?
4 A. Not in detail, no.
5 Q. Well, at any level of
6 detail, even high level of detail?
7 A. Well, I already described
8 what I saw was descriptions made to
9 health authorities following the
10 investigation as to where the potential
11 impurities could have been introduced.
12 [REDACTED]

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1 [REDACTED]
2 BY MR. HONIK:
3 Q. Okay. And when you say
4 that, are you saying that as head of
5 regulatory affairs, you compiled that
6 scientific data and then communicated it
7 to the FDA, is that what you mean?
8 A. I didn't compile any data.
9 As I previously testified,
10 our role in regulatory affairs is to take
11 source documents from the scientists that
12 are responsible for that. And then
13 delivering it to the various health
14 authorities to be responsive to their
15 request.
16 Q. Yeah, I don't want to be
17 unduly semantical because this will
18 take -- this will be a very long day if
19 we do.
20 All I'm really asking you,
21 sir, is this, as a head of global
22 regulatory affairs at Mylan, did you
23 collect the scientific data that
24 reflected the statement that I just read

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1 to you about the presence of azides and
2 triethylamine and then incorporate it in
3 a communication to the U.S. FDA, yes or
4 no?
5 MR. TRISCHLER: Objection to
6 form.
7 THE WITNESS: We collected
8 responses, proposed responses and
9 data from the scientist
10 responsible. And then put that
11 into proper format to present to
12 the various health authorities.
13 BY MR. HONIK:
14 Q. Correct. And in doing so,
15 you were reviewing, on Mylan's behalf, to
16 your regulators at the FDA what the root
17 cause analysis was that your scientists
18 arrived at; isn't that correct?
19 A. We shared the information
20 that was a deliverable from the science
21 teams to the health authorities for them
22 to interpret how they wish.
23 Q. Correct. The FDA and others
24 are left to their own devices to

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1 interpret what Mylan supplied.
2 All I'm asking is, sir, is
3 if it isn't true that in regulatory
4 affairs, and as the head of it for Mylan,
5 you collected the statements of your
6 scientists in describing the root cause
7 presence of NDEA and NDMA to the FDA, yes
8 or no?
9 A. We served as a liaison to
10 the health authority. So as a
11 deliverable from the science team, we
12 would collect that information, put it in
13 the proper format, and then send it to
14 the health authority to respond to their
15 requests.
16 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
6 Q. And if I've understood your
7 general testimony to this point, in using
8 or describing the regulatory affairs
9 function as simply liaison, you're
10 passing along what Mylan scientists are
11 telling you to the FDA, correct?
12 A. Yes. We trust our
13 scientists to provide us with true and
14 accurate information.
15 Q. And when you say that you
16 trust your scientists to provide true and
17 correct information, among the things
18 that you in regulatory affairs do not
19 ever do, is to change their scientific
20 views or opinions in the collectibles; is
21 that fair?
22 A. That's not our role.
23 Q. Okay. Is there any role at
24 Mylan that exists to your knowledge, that

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1 has ever existed, which allows someone to
2 overrule or change the scientific
3 collectibles that you've described?
4 MR. TRISCHLER: Objection to
5 form.
6 THE WITNESS: In regulatory
7 affairs we assumed that the
8 deliverable we get has already
9 been completed and reviewed by
10 whatever management might be
11 needed.
12 So we trust that complete
13 information once we receive it.
14 BY MR. HONIK:
15 Q. And you mentioned by name
16 earlier in your testimony Walt Owens as
17 having a prominent role on the R&D side,
18 correct?
19 A. Early on. I think during
20 this time period, he was in quality. But
21 he was in R&D for some period of time.
22 [REDACTED]

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[REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 BY MR. HONIK:
6 Q. Okay. And more importantly,
7 do you remember seeing statements like
8 that reflecting Mylan's scientific views
9 on the root cause analysis of the
10 presence of these carryover impurities
11 which were then employed by you, the
12 royal you, in regulatory affairs in
13 communicating with the FDA, yes or no?
14 A. As I mentioned before, we
15 received the responses from the
16 scientists and then we would have shared
17 that with the health authorities in
18 response to their queries.
19 Q. I totally understand that.
20 But what I want to learn from you in the
21 course of preparing for today, as a
22 designee for Mylan and the companies, the
23 various entities, if you didn't come to
24 understand what the Mylan scientists had

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1 conveyed to the health authorities in the
2 manner in which I've described to you by
3 quoting Dr. Owens and some other
4 documents from Mylan, yes or no?
5 MR. TRISCHLER: Objection to
6 form. Objection. Asked and
7 answered.
8 THE WITNESS: I have no
9 reason not to believe the
10 statements that you've described
11 to me by Walt Owens.
12 BY MR. HONIK:
13 Q. And more importantly they
14 were reflective of the documents that
15 ultimately were submitted to the FDA in
16 explaining from Mylan's scientific
17 standpoint how these carryover impurities
18 came to be present in valsartan, correct?
19 MR. TRISCHLER: Objection to
20 form.
21 THE WITNESS: We can refer
22 to the documentation that was
23 submitted to the health authority,
24 that would contain a summary of

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1 the investigation once it was
2 completed.
3 BY MR. HONIK:
4 Q. I totally get that. And
5 these are high level preparatory
6 framework-type questions, Mr. Talton.
7 And all I'm trying to
8 understand is, did your understanding of
9 the root cause, as you and I have now
10 been discussing for a few minutes, help
11 to inform and create knowledge for you in
12 preparing for the various topics that
13 you're here to give testimony about?
14 A. When you first asked the
15 question, I explained to you that my
16 understanding was at the conclusion of
17 the investigation, it was a result of the
18 use of recovered solvents.
19 So that is my baseline
20 understanding, and is consistent with
21 what Walt Owens has described.
22 Q. Okay. I appreciate that.
23 And did that also help to inform the
24 balance of your preparation for the

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1 topics today?
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: That's just a
5 baseline understanding. And then
6 I looked at documentation to and
7 from health authorities to support
8 and to get prepared.
9 BY MR. HONIK:
10 Q. Okay. And in sort of plain
11 English, and then we'll move on, in order
12 to be able to testify today on Mylan's
13 behalf, did you acquire a personal and
14 satisfactory understanding of how NDEA
15 and NDMA got into the valsartan that
16 Mylan sold? Do you have any doubts about
17 how that happened in your mind
18 chemically?
19 MR. TRISCHLER: Objection to
20 form.
21 THE WITNESS: As I stated
22 previously, I relied upon the
23 scientists to make that
24 conclusion. So I have no reason

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1 not to believe what they
2 concluded.
3 BY MR. HONIK:
4 Q. Okay. And you've accepted
5 the truths of those scientific inputs
6 from Mylan's scientists to help prepare
7 yourself for testimony today, correct?
8 A. Yes. I relied upon the
9 scientists to provide me with information
10 that was -- that could be used to support
11 a response to health authorities.
12 Q. Thank you. That's very
13 helpful.
14 MR. HONIK: We've been going
15 a little over an hour, why don't
16 we take five or 10 minutes, Clem,
17 and Mr. Talton and we'll resume
18 them.
19 Let's go off the record.
20 THE VIDEOGRAPHER: Okay.
21 The time is 10:39 a.m. Off the
22 record.
23 (Short break.)
24 THE VIDEOGRAPHER: The time

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1 is now 10:51 a.m. Back on the
2 record.
3 BY MR. HONIK:
4 Q. Mr. Talton, welcome back.
5 Are you comfortable and
6 ready to proceed?
7 A. Yes.
8 Q. Before I move into the real
9 substance of my examination of you today.
10 I want to make sure that the record is
11 clear on one thing, which we alluded to
12 and make clear.
13 You understand yourself to
14 be a designee today, and testifying under
15 oath on behalf of the following Mylan
16 entries: One, Mylan Laboratories
17 Limited; is that correct?
18 A. Yeah.
19 Q. Two, Mylan N.V., correct?
20 A. Yes.
21 Q. As well as Mylan
22 Pharmaceuticals Inc.; is that correct?
23 A. Yes.
24 Q. And the preparation that you

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1 described to me earlier before we broke
2 considered each of the entities for whom
3 you are designated to testify, correct?
4 A. Yes. When I say Mylan, I
5 mean Mylan the entity.
6 Q. All of the entities,
7 correct?
8 A. Correct.
9 Q. Sir, do you have in front of
10 you the collection of documents that we
11 sent over and I think would have been
12 hard copied for you?
13 MR. TRISCHLER: Well, it's
14 not -- there's a lot of Styrofoam,
15 and computers between him and the
16 documents, but they're within --
17 they're within arm's reach but
18 they are not in front of him.
19 MR. HONIK: I appreciate
20 that.
21 BY MR. HONIK:
22 Q. Mr. Talton, just a little
23 bit of housekeeping, because Mr. Davis,
24 my associate, has been conducting most of

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1 the Mylan depositions to date.
2 But the convention that
3 we're using to put documents in front of
4 witnesses is as follows:
5 There are documents that
6 have been tabbed that have not previously
7 been used which will be marked anew for
8 today as plaintiff Talton, and then we'll
9 assign a number.
10 Do you understand that?
11 A. Yes.
12 Q. And then as to previously
13 used documents, that is documents
14 employed in earlier depositions of Mylan
15 representatives, we'll refer to them by
16 our previously marked exhibit names and
17 numbers.
18 Do you understand that?
19 A. Yes.
20 Q. Okay. And we have Mr. Davis
21 here, who is going to be our doc jockey
22 if we have any problems so that we can
23 end up with an appropriate index of the
24 documents used today.

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1 Earlier you and I talked a
2 little bit about Matrix. Do you remember
3 that?
4 A. Yes.
5 Q. And Matrix was a company
6 acquired by Mylan, as you told me, in the
7 mid 2000s, and among other things, had a
8 process development lab; is that correct?
9 A. When we acquired Matrix,
10 their primary business was API business,
11 although they had started work in the
12 finished dosage form area.
13 Q. And that existed in what was
14 known as Unit 3 in Jedimettla India?
15 A. I don't recall the specific
16 locations, but I know they do have -- did
17 have a Unit 3 in their network.
18 Q. And at the time that Mylan
19 was going about getting ready to submit
20 its ANDA and DMF in connection with
21 valsartan, do you recall that Matrix did
22 some process development work that helped
23 support those submissions?
24 MR. TRISCHLER: Objection to

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1 form. To the extent that it's
2 beyond the scope.
3 THE WITNESS: I wouldn't be
4 able to be aware of the specifics
5 of what they did. Generally that
6 type of work to be required in
7 order to prepare a drug master
8 file.
9 BY MR. HONIK:
10 Q. Right. Inasmuch as your job
11 drug 2009 and 2014 was to serve as vice
12 president, head of global regulatory
13 affairs operations for Mylan, you oversaw
14 and actually partnered closely with the
15 R&D development teams including the one
16 at Matrix, did you not?
17 A. It would have been one of
18 the functions that we would have
19 interacted with in order to obtain source
20 documents for registration.
21 Q. Precisely. And in fact, in
22 your CV that we looked at and marked
23 Exhibit 1, you said specifically, and I
24 quote, you partnered closely with R&D

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1 development teams to develop and prepare
2 high quality submissions for worldwide
3 registration, correct?
4 A. Yes. I've testified to
5 that.
6 Q. Right. And I'm now bringing
7 it in a more granular way to ask you
8 whether it isn't true that the regulatory
9 affairs operations, including yourself in
10 those years, in 2010, relied upon
11 collectibles from Matrix Labs Limited in
12 India?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: Matrix would
16 have been one of the entities that
17 we may have received a source
18 document to support a
19 registration, if that's what
20 you're asking me.
21 BY MR. HONIK:
22 Q. I am. And indeed, Matrix
23 supplied a source document in connection
24 with a submission for registration for

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1 valsartan; isn't that right?
2 A. It's my understanding they
3 filed a drug master file covering the
4 manufacture of valsartan active
5 pharmaceutical ingredient.
6 Q. And the work product from
7 Matrix was relied upon as a collectible
8 which was then submitted by Mylan
9 regulatory affairs, correct?
10 A. As I previously testified,
11 when referring to a drug master file in
12 an application, you're provided a letter
13 of authorization. So you don't actually
14 submit the drug master file as a
15 deliverable. It's a letter of
16 authorization to have access to the DMF.
17 Q. Okay. Do you -- well, let
18 me ask the question differently.
19 In preparation for today,
20 did you look at any of the work product
21 or collectibles as you've been using the
22 term, from Matrix, as it concerns
23 valsartan?
24 A. I saw documentation to and

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1 from FDA with respect to information
2 requests that were received in connection
3 with the drug master file.
4 Q. Okay. But more specifically
5 in preparation for your testimony today,
6 did you or did you not look at source
7 work that became collectibles in or about
8 2010 that Mylan relied upon from Matrix
9 in connection with the DMF?
10 A. No, I did not look at the
11 drug master file. I looked at
12 correspondence with the health authority.
13 Q. Fair enough. Why don't
14 we -- why don't you turn to, and put in
15 front of you Tab 8, which is an Addendum
16 4 to the valsartan development report
17 prepared by Matrix, which we'll file --
18 excuse me -- which we'll mark as
19 Plaintiff Talton Exhibit 1.
20 MR. TRISCHLER: I thought
21 the CV was Number 1.
22 MR. DAVIS: Ruben, I marked
23 the CV as 1. So 2.
24 MR. HONIK: My bad. Number

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1 2.
2 (Document marked for
3 identification as Exhibit
4 PL-Talton-2.)
5 BY MR. HONIK:
6 Q. Sir, just to orient you to
7 this document -- you have it in hand, do
8 you?
9 A. Yes, I do.
10 Q. The first page, the cover
11 page, is headed Addendum IV to valsartan
12 development report.
13 You have that in front of
14 you?
15 A. Yeah.
16 Q. And at the upper left it's
17 got the heading that conveys Matrix, a
18 Mylan company, Laboratories Limited, Unit
19 3 Jedimettla.
20 Do you see that, sir?
21 A. Yeah.
22 Q. And then to the right of
23 that, it say Matrix Laboratories Limited
24 PD, for process development, Lab Unit 3.

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1 Did I read that correctly?

2 A. Yes.

3 Q. Are you familiar with that

4 lab and unit as part of the Mylan

5 company?

6 A. I know it's one of the

7 facilities within our manufacturing

8 network.

9 Q. Okay. And is it one of the

10 facilities that you, from time to time

11 collaborate with in order to get the kind

12 of collectibles that you've referred to

13 so far in your testimony for submissions

14 to health authorities?

15 A. I wouldn't interact directly

16 with the facility, per se. The person

17 responsible for the drug master file area

18 would be the person that I would most

19 likely reach out to.

20 Q. Okay. So there's an

21 intermediary. But nonetheless, this

22 would be among the Mylan facilities that

23 could, from time to time, provide

24 scientific information incorporated in a

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1 submission or filing to a health

2 authority, correct?

3 A. Yes.

4 Q. Now, to orient you to the

5 document, it's agreed it's very poorly

6 paginated, but do you see the faint page

7 markings, 01 ending in 70, being the last

8 page?

9 A. Yes.

10 Q. To be sure, I'm not going to

11 take you through the entire document.

12 But I do want to go through and ask you

13 some questions about specific pages. Are

14 you with me?

15 A. Yes.

16 Q. So if we turn to the second

17 page, marked 02, we see a continuation of

18 the Matrix designee, a Mylan company. It

19 refers again to Addendum IV, to the

20 valsartan development report.

21 Let me ask you, if I could.

22 What is a valsartan development report?

23 MR. TRISCHLER: Objection to

24 form.

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1 THE WITNESS: I would assume

2 it would be a report that would

3 describe the development of the

4 API.

5 BY MR. HONIK:

6 Q. And when you use the phrase

7 or term development of the API, what do

8 you mean?

9 A. Development of the

10 manufacturing process for a specific

11 molecule.

12 Q. Okay. And by development of

13 the specific process, you are talking

14 about what colloquially be referred to as

15 the chemistry recipe for manufacturing,

16 in this case valsartan API, correct?

17 MR. TRISCHLER: Objection to

18 form.

19 THE WITNESS: I would

20 probably refer to a synthetic

21 process, not a recipe.

22 BY MR. HONIK:

23 Q. Thank you. I appreciate

24 that. I'll use that term in place of it.

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1 So this document reflects

2 Mylan's internal description of the

3 synthetic process of the valsartan API,

4 correct?

5 MR. TRISCHLER: Objection to

6 form. Scope.

7 THE WITNESS: That would be

8 part of it. I mean, the

9 development report is more

10 comprehensive than just the

11 synthesis. But the synthesis

12 would be included.

13 BY MR. HONIK:

14 Q. No doubt. And indeed, this

15 document marked Exhibit 2 is simply

16 Addendum IV, correct?

17 A. That's how it's labeled.

18 Q. And presumptively, there are

19 a variety of addenda to the report that

20 reflect different aspects of the

21 synthesis process and other elements,

22 correct?

23 A. I'm not familiar with the

24 other addendums.

<p style="text-align: right;">Page 114</p> <p>1 Q. Okay. Fair enough. But 2 we're looking at Addendum IV. And if we 3 look together at Page 2, we see that the 4 relevant signoffs and dates are all in 5 2010, in fact December. 6 Do you see that? 7 MR. TRISCHLER: Objection to 8 form. 9 THE WITNESS: It does appear 10 that each of the signatures 11 occurred in late 2010. 12 BY MR. HONIK: 13 Q. And I presume at Mylan, this 14 signoff page here, in the front of the 15 addendum of Exhibit 2, are by the various 16 managers, if you will, who are designated 17 to review, approve, and then signoff on 18 this development report; isn't that 19 right? 20 MR. TRISCHLER: Objection to 21 form and scope. 22 THE WITNESS: Yeah, I'm not 23 sure of the responsibilities. 24 BY MR. HONIK:</p>	<p style="text-align: right;">Page 116</p> <p>1 just say if you don't know the answer to 2 one of my questions or it calls for rank 3 speculation, it's perfectly fine for you 4 to tell me that you don't know or you'd 5 be speculating. Okay? 6 A. Yep. 7 Q. We have someone identified 8 as the assistant manager of the process 9 development lab who signed off on this, 10 correct? 11 MR. TRISCHLER: Objection to 12 form. 13 THE WITNESS: There is a 14 signature by someone by that name 15 and designation. 16 BY MR. HONIK: 17 Q. And similarly, there's 18 somebody designated as an officer of the 19 production development lab who similarly 20 signed off in December of 2010, correct? 21 A. There is someone that signed 22 off as representing officer of PDL. 23 Q. Okay. And is it -- is it a 24 fair assumption on my part when we look</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Okay. But if we look 2 together on Page 2, the designation of 3 the people at Mylan, signing off on it, 4 include, among others, the head of 5 quality, correct? 6 A. Yes. 7 Q. And somebody known as the 8 AVP of the -- I presume that's process 9 development lab. Do you know what that 10 is, AVP of the process development lab? 11 A. No, I do not. Assistant 12 vice president I would assume. But I'm 13 not sure. 14 Q. That's my assumption as 15 well. And then we've got somebody at the 16 process development lab with the title or 17 acronym DGM. Is that general manager? 18 MR. TRISCHLER: Objection to 19 form. 20 THE WITNESS: I don't know. 21 I can't speculate as to what those 22 acronyms or abbreviations mean. 23 BY MR. HONIK: 24 Q. That's fine. And let me</p>	<p style="text-align: right;">Page 117</p> <p>1 at the contents of this document, having 2 seen the signoff page on Page 2 together, 3 that each of the aforementioned designees 4 on behalf of Mylan reviewed and signed 5 off on the contents? 6 MR. TRISCHLER: Objection. 7 Beyond the scope. 8 THE WITNESS: I don't know 9 the process by which they used to 10 review and signoff on documents. 11 So again, I would be 12 speculating to answer that 13 question. 14 BY MR. HONIK: 15 Q. Well, the way I phrase the 16 question is, do you have some other 17 understanding of what these signoffs 18 mean, other than these folks looked at 19 the content of this development report 20 and signed their names to it in December 21 of 2010? 22 MR. TRISCHLER: Objection. 23 Beyond the scope. Objection. 24 Asked and answered.</p>

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1 THE WITNESS: I don't know
2 what their representation is or
3 signature means on this. That's
4 out -- outside of my knowledge of
5 what their documentation practices
6 were at the time.
7 BY MR. HONIK:
8 Q. Did you have a different
9 deductive assumption about it than mine,
10 that they reviewed and signed off on
11 this?
12 MR. TRISCHLER: Objection.
13 Calls for speculation.
14 You already told him not to
15 speculate and asked him to tell
16 you if he was. And he did. And
17 you're just asking him a third
18 time.
19 Objection. Asked and
20 answered.
21 BY MR. HONIK:
22 Q. You can answer.
23 A. As I previously testified,
24 signatures represent. So I can't

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1 speculate as to what their documentation
2 practices would have been at the time.
3 Q. I get that you don't know
4 what the review protocols or practice is.
5 But my question as phrased is this, sir,
6 and then I'll move on.
7 My deduction is simply that
8 in some way or another, these folks
9 looked at the report, reviewed it and
10 signed off.
11 Is that an unfair deduction
12 to make?
13 MR. TRISCHLER: Objection to
14 form.
15 Objection. Beyond the
16 scope.
17 Objection. Asked and
18 answered.
19 THE WITNESS: The answer is
20 I don't know what their
21 documentation practices were. So
22 I can't speculate as to what their
23 signatures represent or mean.
24 BY MR. HONIK:

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1 Q. Well, have you seen a
2 development report other than this one,
3 before today, in your many years as
4 the -- as a regulatory affairs
5 professional at Mylan?
6 A. These are not the type of
7 reports that I routinely receive or
8 review.
9 Q. Okay. My question is have
10 you nonetheless seen some form of a
11 development report in connection with
12 your work as a regulatory affairs
13 professional at Mylan?
14 A. I've seen a variety of
15 documents that were signed off as a
16 deliverable that were provided to us.
17 Q. That's precisely my
18 question. And although the physical
19 appearance of the signoff page may be
20 different from submission to submission
21 or collectible to collectible, you've
22 nonetheless had decades of experience of
23 reports coming to your desk as a
24 regulatory affairs senior professional at

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1 Mylan in which some underling has
2 reviewed and signed off on whatever the
3 submission is. You've seen that, have
4 you not?
5 A. We receive multiple
6 documents that have signatures on them.
7 Q. Okay. And when you receive
8 them, do they imply to you that somebody
9 in the sort of chain of authority has
10 reviewed it at Mylan and has signed off
11 on them?
12 A. I don't question what their
13 signature means. What I'm looking for is
14 a deliverable. And if it's delivered to
15 regulatory affairs, then we assume it's a
16 technically complete document and
17 suitable for submission into an
18 application.
19 Q. What is a technically
20 complete document?
21 A. Something that's complete.
22 Ready for submission to a health
23 authority.
24 Q. And does that include review

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1 and signoff by a responsible designee?
2 A. It may.
3 Q. Okay. So you've had the
4 experience of having a submission to you
5 which is technically complete for a
6 document which includes a signoff; is
7 that correct?
8 A. I have already answered
9 that. We receive a variety of documents
10 that may contain signatures for inclusion
11 into a regulatory filing.
12 Q. And does Exhibit 2 look like
13 such a document, that is to say, reviewed
14 and signed off by someone at Mylan as to
15 its contents? Does this look like that?
16 A. You're asking a question
17 that I can't answer, because it depends
18 on what their documentation practices are
19 locally at that time in 2010, and what
20 each of their signatures represents.
21 I don't know that. I'm not
22 familiar with that. So I'm not going to
23 be able to answer that question.
24 Q. I'll ask it one more way,

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1 and then we'll move on.
2 What could this possibly
3 mean in your experience, sir, other than
4 the aforementioned designees reviewed the
5 contents of this development report and
6 then signed off their approval? What
7 could it mean other than that?
8 MR. TRISCHLER: Objection.
9 Asked and answered.
10 THE WITNESS: I can't answer
11 the question because I don't know
12 what their documentation practices
13 were at the time.
14 BY MR. HONIK:
15 Q. I understand. But based on
16 your experience, having received, as
17 you've told me, technically completed
18 documents, which in some instances
19 included signoffs, for my edification,
20 Mr. Talton, what could this possibly mean
21 other than these designees reviewed the
22 contents and signed off their approval to
23 it, other than that?
24 MR. TRISCHLER: Objection.

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1 Asked and answered.
2 THE WITNESS: I can't
3 speculate as to what their
4 signatures mean, because I'm not
5 familiar with the documentation
6 practices in 2010.
7 BY MR. HONIK:
8 Q. Turn, if you will, to
9 Page 6. This is a section marked 3.0.
10 And it's titled "detailed laboratory
11 process."
12 Do you see that?
13 A. Yes.
14 Q. And this is Mylan process
15 development scientists identifying the
16 raw materials that go into valsartan API,
17 correct?
18 MR. TRISCHLER: Objection to
19 form.
20 Objection. Beyond the
21 scope.
22 THE WITNESS: It appears to
23 be a list of raw materials which
24 are used to manufacture a specific

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1 step within the synthesis maybe.
2 Again, I haven't seen this
3 document before.
4 BY MR. HONIK:
5 Q. Right. And the step within
6 the synthesis that you're referring to is
7 valsartan API, right?
8 A. On Page 6 it talks about
9 VLN-1, which in my interpretation would
10 be the intermediate, not the API.
11 Q. Okay. VLN is a process code
12 that refers to one of two steps in the
13 manufacture of valsartan API, right?
14 A. I don't know. I have not
15 reviewed the drug master file so I'm not
16 familiar with this document.
17 Q. Well, let me take a step
18 back, Mr. Talton. I'm a little
19 surprised.
20 Are you not aware as a
21 designee of Mylan today that VLN was one
22 of the process codes for valsartan that
23 was sold in the United States of America?
24 MR. TRISCHLER: Object to

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1 the form of the question.
2 I'm not sure that your
3 surprise is relevant to anything.
4 Objection to form.
5 Argumentative.
6 THE WITNESS: I'm aware that
7 we have a drug master file that
8 was prepared by MLL which
9 contained multiple processes in it
10 over its lifecycle.
11 BY MR. HONIK:
12 Q. Right. And one of my -- and
13 my question is, is not one of the process
14 codes that was used by Mylan to create
15 valsartan API, and valsartan finished
16 dose, VLN?
17 A. I would not be able to
18 answer that question without looking at
19 the actual drug master file that we were
20 authorized to reference.
21 Q. Okay. Sitting here today,
22 you don't know that VLN is one of the
23 process codes for recalled valsartan in
24 the United States? Is that your

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1 testimony?
2 A. My testimony is there was
3 multiple processes, in my understanding,
4 in the drug master file. So I'm not
5 familiar with every -- every potential
6 process that might have been registered.
7 Q. Okay. Do you know if VLN
8 was one of them that was registered?
9 A. Not without looking at the
10 original drug master file and seeing what
11 processes were described within it.
12 Q. Do you know if VST was one
13 of the process codes that was registered
14 for valsartan?
15 A. I am familiar with seeing
16 reference to VST, because that was
17 described in some of our documentation as
18 part of our investigation.
19 Q. So is your answer yes, that
20 VST corresponds to a valsartan code?
21 A. Yes. I'm familiar. I saw
22 documentation that made reference to a
23 VST process and VAA process. But I don't
24 recall VLN.

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1 Q. Okay. Nonetheless, if we
2 return to Page 6 of Exhibit 2, you agree
3 that this entire document relates to a
4 valsartan development report. And as you
5 pointed out to me, this is but one step
6 in it, correct?
7 A. That's my interpretation
8 from looking at this document for the
9 very first time.
10 Q. And among the steps and raw
11 materials identified on Page 6 of
12 Exhibit 2 is triethylamine.
13 Do you see that?
14 A. That is one of the raw
15 materials listed.
16 Q. And there is a parenthetical
17 reference with the letters F/R and that
18 stands for fresh and recovered, correct?
19 MR. TRISCHLER: Objection to
20 form.
21 THE WITNESS: I don't know.
22 BY MR. HONIK:
23 Q. You don't know what F and R
24 means in that context?

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1 A. No, I do not.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
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Page 134

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

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20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 137

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 BY MR. HONIK:

7 Q. Turn, if you will, to Page

8 21. Before we move from this document,

9 do you see this heading, 4.0, critical

10 process parameters and additional

11 studies?

12 A. Yes.

13 Q. Are you familiar with what

14 those terms refer to or mean?

15 A. Not in context with an API

16 product development report, no.

17 Q. Okay. Do you see the first

18 sentence below that heading where it

19 refers to critical process parameters and

20 risk assessments?

21 Do you see that?

22 A. Yes.

23 Q. Can you tell me your

24 understanding of what those terms mean?

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1 A. I'm not familiar with the
2 process by which they followed in order
3 to develop and prepare a drug master
4 file. So I can't comment on what that
5 means.

6 Q. Okay. Did you have any
7 understanding of a critical process
8 parameters refers to in any context in
9 which you've discharged your job
10 responsibilities?

11 MR. TRISCHLER: Objection to
12 form.

13 THE WITNESS: My
14 interpretation or assumption would
15 be that it describes process
16 parameters that are used that are
17 considered important or critical
18 to the manufacturer.

19 BY MR. HONIK:

20 Q. Thank you.

21 How about the term "risk
22 assessment," or "assessments" plural?
23 What definition do you apply to that?
24 A. I can't speculate as to what

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1 risk assessment means in the context of
2 this document, because again this is
3 outside the scope of any document that I
4 routinely look at in my role.

5 Q. Right. So I'm not asking
6 you the question in context -- in the
7 context of this document, per se,
8 Exhibit 2.

9 But in your many years as
10 both a chemist and a regulatory affairs
11 professional, what does the term "risk
12 assessment" or "assessments" mean to you?

13 A. Personally? I'm not sure
14 what the scope of the question here is.

15 Q. I'm asking if you understand
16 what risk assessment means.

17 A. Well, risk assessment can
18 mean a lot of different things. It
19 depends on the context about which it's
20 written.

21 Q. Okay. How about in
22 connection with a development report such
23 as this?
24 MR. TRISCHLER: Objection.

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1 Beyond the scope.

2 THE WITNESS: I've already
3 testified that I -- I can't answer
4 that in context with this
5 document.

6 MR. HONIK: Let's mark as
7 Talton Exhibit 3, Addendum Tab 7,
8 or Tab 7.

9 (Document marked for
10 identification as Exhibit
11 PL-Talton-3.)

12 BY MR. HONIK:

13 Q. Do you have that in front of
14 you, Mr. Talton?

15 A. Yes.

16 Q. You see, do you not, this is
17 another section of the same valsartan
18 development report prepared by Matrix.

19 Do you see that generally?

20 A. Yes. It's labeled valsartan
21 development report, Addendum 1.

22 Q. Right. So this was yet
23 another addendum to the same larger
24 development report prepared by Mylan's

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1 scientists, correct?

2 A. It is not possible to say
3 this is the same addendum that goes with
4 that one, because it's not paginated or
5 otherwise referenced. But I would assume
6 that it is.

7 Q. Okay. And that's because
8 it's called valsartan development report
9 and if you turn to the second page of the
10 document, Exhibit 3, you see that it's
11 signed off on by three designees of Mylan
12 in 2009, right?

13 MR. TRISCHLER: Objection to
14 form.

15 THE WITNESS: The document
16 does contain three signatures and
17 it was signed off in 2009.

18 BY MR. HONIK:

19 Q. Right, by Mylan scientists
20 in connection with this valsartan
21 development report, correct?

22 MR. TRISCHLER: Objection to
23 form. Foundation.
24 THE WITNESS: It's a Matrix

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1 report. So, yes, I would assume
2 they would be Matrix employees.
3 BY MR. HONIK:
4 Q. And to be clear, they're
5 Mylan employees, right?
6 MR. TRISCHLER: Objection to
7 form.
8 THE WITNESS: Matrix would
9 have been part of the Mylan
10 network in 2009.
11 BY MR. HONIK:
12 Q. Right. And that means that
13 these were Mylan process development
14 chemists working for Mylan in connection
15 with the development or synthesis of
16 valsartan, correct?
17 A. I'm not sure I can say
18 definitively that they are development
19 scientists. But their roles or
20 designations are described here.
21 Q. And importantly, they were
22 doing this at the behest and direction of
23 Mylan, correct?
24 MR. TRISCHLER: Objection to

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1 form.
2 THE WITNESS: I can't -- I
3 can't definitively say that it was
4 done at the direction of Mylan. I
5 mean, Matrix had an API business
6 at the time that we acquired them.
7 This is part of their ongoing
8 routine business.
9 BY MR. HONIK:
10 Q. Do you have a moment's
11 doubt, Mr. Talton, that this valsartan
12 development report done by Matrix
13 scientists was done at the behest of
14 Mylan? Do you have any doubt about
15 that?
16 MR. TRISCHLER: Objection.
17 Beyond the scope.
18 THE WITNESS: There's no way
19 I can know that specifically.
20 Like I said, they had an API
21 business. They developed APIs
22 for -- for sale, not just for use
23 in Mylan products, but for other
24 customers as well. There's

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1 multiple APIs they have that Mylan
2 doesn't even utilize.
3 BY MR. HONIK:
4 Q. Turn to Page 7 of this
5 document, Exhibit 3. It's headed
6 Section 4, "Detailed Laboratory Process."
7 Do you see that?
8 A. Yeah.
9 Q. As much as the signoffs are
10 in 2009, just to frame the timeline here,
11 Mylan's ANDA approval for valsartan
12 occurred in 2012, right?
13 A. I'd have to go back and look
14 at the specific date. I'm sorry. I
15 don't recall.
16 Q. But in preparation for
17 today, you know that there were actually
18 three ANDA-approved valsartan products.
19 Two were combination, and one was
20 straight or pure valsartan, correct?
21 A. Yes, I'm aware of three
22 approval Mylan ANDAs that contained
23 valsartan.
24 Q. And would you disagree that

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1 the earliest of those would have occurred
2 in September of 2012?
3 A. I didn't go back and look at
4 the approval so I didn't memorize the
5 approval dates for the applications.
6 That time frame sounds about right, but I
7 would have confirm the approval to answer
8 your question specifically.
9 Q. And at a high level,
10 regulatory affairs in connection with
11 submissions for that ANDA, is collecting,
12 among other things, development reports
13 just like this one, correct?
14 MR. TRISCHLER: Objection to
15 form. Misstates testimony.
16 THE WITNESS: You know, as a
17 previously testified, a drug
18 master file is a separate --
19 separate registration that's
20 confidential.
21 So as an applicant for
22 valsartan tablets or one of
23 combination products, Mylan forms
24 would have included a letter of

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1 authorization that would have
2 allowed FDA to review the drug
3 master file on our behalf.
4 So we would not have had
5 access or reviewed this
6 documentation in preparation of
7 our ANDA.
8 BY MR. HONIK:
9 Q. And I haven't asked you that
10 really, Mr. Talton.
11 All I'm asking is if it
12 isn't true that part of the process to
13 get to market by Mylan and sell
14 valsartan, that there were two tracks:
15 Collection of materials to submit for the
16 ANDA, and separately a DMF, correct?
17 A. Yes, there was a drug master
18 file that we referred to, and then
19 there's other documents to support the
20 manufacture of the finished dosage form.
21 Q. And among the documents that
22 are relied upon to support those
23 submissions would be a development report
24 like the one we're looking at here,

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1 right?
2 A. Most likely, yes. But these
3 are not the type of documents that we
4 would typically see in regulatory
5 affairs.
6 Q. Well, I didn't ask you
7 whether you'd see it typically or
8 otherwise in regulatory affairs, simply
9 that this type of development report is
10 routinely developed and relied upon at
11 Mylan for one or both of those track
12 submissions, right?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: This is the
16 type of report that would most
17 likely be prepared in preparation
18 of a drug master file. But
19 previously you had asked me was
20 this the type of document that we
21 would have collected.
22 So I was trying to answer
23 your specific question by saying
24 no, this is not the type of source

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1 document that we would normally
2 collect within regulatory affairs
3 to prepare an ANDA.
4 BY MR. HONIK:
5 [REDACTED]

Page 149

1 [REDACTED]

Page 150

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 MR. HONIK: Let's call up

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1 another exhibit.
2 This has been previously
3 marked as Snider-19.
4 (Previously marked
5 PL-Snider-19.)
6 MR. TRISCHLER: Hey, Ruben,
7 were those -- was that among the
8 stack that was sent. Because I
9 didn't bring in any prior exhibits
10 unless it was sent this morning.
11 MR. HONIK: Maybe John can
12 answer whether the previously
13 marked exhibits were part of any
14 link.
15 MR. DAVIS: Yes, they would
16 have been. Which one are you
17 referring to?
18 MR. HONIK: Snider-19.
19 MR. TRISCHLER: Okay. I
20 think I found -- I think I found
21 them.
22 Ruben, the prior agreement
23 that we've had, we've not been
24 looking at any of these exhibits

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1 before you call them out.
2 But in flipping through them
3 now, there's different -- there's
4 Gomas exhibits, Snider exhibits.
5 Do you mind if I have Frank
6 separate them so we can move this
7 a little quicker as we go through.
8 I won't show any of them to
9 the witness before you call them
10 out.
11 MR. HONIK: I think that
12 makes perfect sense. Why don't we
13 go off the video record and allow
14 you a little time to do that.
15 MR. TRISCHLER: Okay.
16 THE VIDEOGRAPHER: The time
17 is 11:37 a.m. Off the record.
18 (Short break.)
19 THE VIDEOGRAPHER: The time
20 now is 11:42 a.m. Back on the
21 record.
22 BY MR. HONIK:
23 Q. So Mr. Talton, I know we
24 went off the record to pull some

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1 documents including the next one that I'd
2 like to review with you, which is
3 Snider-19. And I presume that you have
4 it in front of you.
5 But what I'm hoping as well
6 that documents that we've already marked
7 and used are within arm's reach of you or
8 someone who can hand it to you.
9 And before we leave
10 Exhibit 3, which is the development
11 report that we had been looking at, I
12 just want to ask you a couple of quick
13 questions, okay?
14 Do you have that back in
15 front of you, Exhibit 3?
16 A. Yeah.
17 Q. So we looked together, and I
18 understand that you're not familiar
19 personally with this document, you're
20 seeing it for the first time. We've
21 nonetheless established that it was
22 prepared by Matrix chemists at the
23 direction of Mylan.
24 But on Page 16, the process

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1 for recovery of o-xylene, we looked at
2 that together, correct?
3 A. Yes. We referred to Page 16
4 previously.
5 [REDACTED]

Page 155

1 [REDACTED]

Page 156

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 BY MR. HONIK:
6 Q. Precisely. Thank you for
7 clarifying that. So if we turn now to
8 Snider-19. Do you have that document in
9 front of you?
10 A. Yes.
11 MR. HONIK: And for the
12 record, we're going to mark this
13 Talton Exhibit 4, I think we're up
14 to --
15 MR. DAVIS: Ruben, let's not
16 re-mark per our procedure.
17 MR. HONIK: The convention
18 is that we're going to call it
19 Snider-19.
20 BY MR. HONIK:
21 Q. If we look at it together
22 Mr. Talton, on marked Page 1, which is
23 actually Page 2 of the Exhibit Snider-19,
24 you see that it's part of the drug master

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1 file, correct?
2 A. Yes, it appears to be a
3 section in the drug master file for
4 valsartan.
5 Q. Correct. And specifically
6 it's Section 3.2.S.3.
7 Do you see that?
8 A. Yes. 3.2.S.3.2.
9 Q. And the entirety of the
10 exhibit, Snider-19, is 83 pages. The
11 second page being Page 1 and the last
12 page being Page 82. Do you have it that
13 way?
14 A. Yes.
15 Q. Did you look at any part of
16 this in preparation for your testimony
17 today?
18 A. No, I did not review the
19 drug master file.
20 Q. I don't mean to be
21 impertinent. But is there a reason that
22 you didn't look at the DMF for valsartan
23 in preparation for your designated
24 testimony today?

<p>Page 158</p> <p>1 A. It's not something that I 2 would routinely review as the normal 3 course of my business, nor did I think it 4 was necessary in order to testify today. 5 Q. Okay. Is that a conclusion 6 that you arrived at on your own? 7 A. Yes. 8 Q. Okay. Did you not think 9 that the elements of the valsartan DMF 10 would not have some relationship or 11 import to any of the topics that you've 12 been designated to testify about? 13 A. As I've testified on several 14 occasions this is a scientific document 15 compiled by scientists. And the 16 investigation made reference to the drug 17 master file, but I was prepared to talk 18 about communications with and to and from 19 the health authorities, not the content 20 of the specific DMF. 21 Q. Well, to my thinking 22 Mr. Talton, and that begs the question 23 whether you think the scientific 24 impressions in the DMF, or otherwise, by</p> <p>Page 159</p> <p>1 Mylan scientists impacted the 2 communications with regulators. Yes or 3 no? 4 MR. TRISCHLER: Objection to 5 form. 6 THE WITNESS: Could you 7 repeat that question? 8 BY MR. HONIK: 9 Q. Yeah. I'm just 10 understanding whether you came to believe 11 in preparation for today whether the 12 views of Mylan's scientists in the DMF 13 and otherwise, would have any impact to 14 any of the topics that you're designated 15 to give testimony on? 16 MR. TRISCHLER: Objection to 17 form. 18 THE WITNESS: Communications 19 from the scientists to the health 20 authority, I was involved with, 21 which is what I'm prepared to 22 testify about, but not the 23 contents of the specific document 24 which we don't see in the normal</p>	<p>Page 160</p> <p>1 course of business. 2 BY MR. HONIK: 3 Q. Right. I take your point 4 that in the normal course of business you 5 might not see it. 6 But today you're outside 7 your normal course of business, because 8 you've been designated by Mylan to answer 9 questions on a number of topics including 10 communications with regulators. 11 And so the question, and 12 then I'll move on, is, did you not think 13 that acquainting yourself with the DMF 14 would help inform your answers today? 15 A. Any communication with the 16 health authority would have been directly 17 in communication with the health 18 authority, not the content of the DMF. 19 The DMF is a still document. It's not an 20 interactive document. 21 Q. Did anyone tell you not to 22 review the DMF in this case? 23 A. No. 24 Q. So if we look at Snider-19,</p> <p>Page 161</p> <p>1 we've already established you recognize 2 this as a particular section of the 2013 3 DMF submitted by Mylan Labs, right? 4 A. It appears to be a section 5 from the drug master file for valsartan. 6 Q. And this -- and I think 7 you've told me this, but you've never 8 seen prior to today any part of the 2013 9 DMF submission; is that correct? 10 MR. TRISCHLER: Objection. 11 Asked and answered. 12 THE WITNESS: I have not 13 reviewed the drug master file for 14 valsartan prior to today. 15 BY MR. HONIK: 16 Q. Okay. Do you see how this 17 section that we're looking at, commencing 18 on Page 1 which is Page 2 of the exhibit, 19 is entitled impurities? 20 A. Yes. 21 Q. And the very first sentence 22 under that heading reads, "The possible 23 impurities of valsartan were synthesized 24 in R&D."</p>
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<p style="text-align: right;">Page 162</p> <p>1 Can you tell me what that 2 means? 3 A. My interpretation would be 4 that the impurities were synthesized in 5 order to characterize them. 6 Q. Okay. And does that entail 7 looking into possible impurities, that 8 is, looking at the process chemistry and 9 determining whether impurities are 10 present or could be present? 11 A. I would interpret this as a 12 list of the potential impurities in the 13 API. 14 Q. Okay. And do you know 15 whether that undertaking by scientists to 16 any degree involves risk assessment? 17 A. I don't know. 18 MR. TRISCHLER: Objection. 19 Beyond the scope. 20 THE WITNESS: I don't know. 21 I'm not familiar with the 22 processes they followed -- 23 BY MR. HONIK: 24 Q. Okay.</p>	<p style="text-align: right;">Page 164</p> <p>1 genotoxic impurity is? 2 MR. TRISCHLER: Objection to 3 form. 4 THE WITNESS: I mean in 5 general, but I'm not a 6 pharmacologist or a toxicologist. 7 So I really can't describe it in 8 detail. 9 BY MR. HONIK: 10 Q. Point taken. Neither am I. 11 Do you -- what is your 12 definition of a genotoxic impurity? 13 A. A potential impurity that 14 could have a serious adverse effect 15 long-term. 16 Q. Okay. On human health? 17 A. Well, whatever species. 18 Yes, if a human is taking the drug 19 potentially, yeah. 20 Q. Right. And if an animal 21 took it, another animal, it would 22 implicate animal health, correct? 23 A. Yeah, it's a health -- it's 24 a health consequence. It's a health --</p>
<p style="text-align: right;">Page 163</p> <p>1 A. -- to develop APIs. 2 Q. Do you see how on this page 3 that we're looking at together category 4 or Item IV is genotoxic impurities? 5 MR. TRISCHLER: Objection to 6 form. 7 THE WITNESS: I do see a 8 reference to that on this page. 9 BY MR. HONIK: 10 Q. Do you know what a genotoxic 11 impurity is? 12 MR. TRISCHLER: Objection to 13 form. Beyond the scope. 14 THE WITNESS: I'm not a 15 toxicologist. 16 BY MR. HONIK: 17 Q. Okay. I know you're not a 18 toxicologist. The question is, as 19 someone with a master's in chemistry, who 20 worked in chemistry, and has for nearly 21 40 years been a regulatory affairs 22 professional at the highest level at 23 Mylan, do you or do you not have a 24 working definition in your mind of what a</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. Precisely. It's a health 2 consequence. 3 Is NDEA a genotoxic 4 impurity? 5 MR. TRISCHLER: Objection. 6 Beyond the scope. 7 THE WITNESS: Based on -- 8 based on the investigation that 9 was concluded and the health 10 authority inquiries, it was 11 referred to as a genotoxic 12 impurity, if I recall. 13 BY MR. HONIK: 14 Q. And similarly, is NDMA a 15 genotoxic impurity? 16 MR. TRISCHLER: Objection. 17 Beyond the scope. 18 THE WITNESS: I think based 19 on the inquiries from the various 20 health authorities they were -- 21 they were bucketed under the 22 category of nitrosamines which 23 would include both of those 24 compounds.</p>

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1 BY MR. HONIK:
 2 Q. Thank you. So if we turn
 3 together to the last page of Snider-19
 4 which is Page 82. Do you see at the top,
 5 kind of a grid -- or it's not a graph,
 6 it's a grid with certain batch numbers
 7 and azide content.
 8 But then if you look at
 9 language below that, do you see the
 10 paragraph that begins, "Other than sodium
 11 azide?"
 12 A. I'm on the wrong page.
 13 Because there's a page number with
 14 exhibit and then -- there's two page
 15 numbers.
 16 Could you clarify which
 17 page?
 18 Q. I'm referring to the very
 19 last page of Snider-19. And at the lower
 20 right-hand corner it's referred to as
 21 Page 82.
 22 A. Okay. I'm there now. Thank
 23 you.
 24 Q. Is that also the last page

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1 of your document Snider-19?
 2 A. It is. When you said 19, I
 3 thought you meant Page 19. That's -- my
 4 apologies.
 5 Q. No problem. And just to
 6 back up or frame the question.
 7 Regardless of your personal
 8 interaction or regulatory affairs'
 9 interaction with DMF, this is the DMF
 10 that Mylan sent in to the FDA, right?
 11 A. Mylan Laboratories sent in,
 12 yes.
 13 Q. Okay. So the contents of
 14 this submission are statements conveyed
 15 from Mylan to the U.S. Food and Drug
 16 Administration, correct?
 17 A. Yeah. It's a regulatory
 18 document that's submitted to the health
 19 authority, yes.
 20 Q. And the contents are
 21 statements that are being conveyed in
 22 this case by Mylan to the U.S. FDA,
 23 correct?
 24 A. The document is being

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1 submitted to the FDA, yes.
 2 Q. Okay. And so if we look in
 3 the middle of Page 82 of Snider-19, the
 4 exhibit so marked previously, do you see
 5 the language that begins, "Other than
 6 sodium azide."
 7 Do you see that paragraph?
 8 MR. TRISCHLER: Objection to
 9 form.
 10 THE WITNESS: Yes.
 11 BY MR. HONIK:
 12 Q. I'm going to read that. It
 13 reads, and I quote: "Other than sodium
 14 azide, none of the intermediates or other
 15 input materials or other process-related
 16 impurities is with structural features
 17 indicative of genotoxic characteristics.
 18 Neither are they capable of giving rise
 19 to such side reactions resulting in
 20 products with genotoxic potential."
 21 Did I read that correctly?
 22 MR. TRISCHLER: Objection to
 23 form.
 24 THE WITNESS: That's what's

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1 written on this page.
 2 BY MR. HONIK:
 3 Q. And is not Mylan conveying
 4 in this DMF submitted to the FDA that
 5 valsartan has no genotoxic
 6 characteristics, nor is it capable of
 7 giving rise to genotoxic potential.
 8 Isn't that what Mylan is conveying?
 9 MR. TRISCHLER: Objection to
 10 form.
 11 THE WITNESS: Based on the
 12 information available at the time,
 13 that was the statement that was
 14 included in the drug master file.
 15 BY MR. HONIK:
 16 Q. Precisely. That's all I'm
 17 getting at, this confirms that Mylan is
 18 confirming to the FDA in 2013, by the
 19 submission of this document, that there
 20 are no genotoxic impurities, nor can
 21 there be any genotoxic impurity potential
 22 in valsartan, correct?
 23 MR. TRISCHLER: Objection to
 24 form.

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1 THE WITNESS: That paragraph
2 that you read to me, if within
3 the submission, that's based on
4 information available at the time.
5 BY MR. HONIK:
6 Q. And to the extent that
7 there's any doubt in what I just asked
8 you and you confirmed, the next paragraph
9 does that because it says, and I quote:
10 "It is, therefore, concluded that the
11 input materials" -- do you see the term
12 "input materials"?
13 A. Yes.
14 Q. And that includes raw
15 materials, right?
16 MR. TRISCHLER: Objection to
17 form.
18 THE WITNESS: I would assume
19 that would mean any material used
20 in the process.
21 BY MR. HONIK:
22 Q. It goes on to state:
23 "Intermediates and other process-related
24 and degradant impurities in valsartan are

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1 neither genotoxic nor do they contribute
2 genotoxic characteristics to the drug
3 substance."
4 Do you see that sentence?
5 A. Yes.
6 Q. And at least the plain
7 reading I attached to it, Mr. Talton, and
8 you can tell me if you agree, is Mylan
9 conveying to the FDA that there's nothing
10 in valsartan that's either genotoxic or
11 can contribute to genotoxic
12 characteristics to that drug, correct?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: Those two
16 paragraphs are contained within
17 this section, and was true and
18 accurate information at that time.
19 BY MR. HONIK:
20 Q. And the paragraph that we're
21 looking at together concludes -- it goes
22 beyond the statement and says, "Hence,
23 Mylan/valsartan complies with the, quote,
24 guideline on the limits of genotoxic

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1 impurities. And then gives a cite to a
2 very specific document from the EMEA from
3 2006."
4 Do you see that?
5 MR. TRISCHLER: Objection to
6 form.
7 THE WITNESS: Yeah. I see a
8 reference to the European guidance
9 document.
10 BY MR. HONIK:
11 Q. And do you agree that what
12 that punctuates and underscores, is Mylan
13 saying to the U.S. FDA, not only doesn't
14 valsartan have any genotoxic
15 characteristics or is it capable of
16 producing such characteristics, but we,
17 Mylan, are in compliance with the
18 specific guideline issued by the EMEA.
19 Isn't that what that says?
20 MR. TRISCHLER: Objection to
21 form.
22 THE WITNESS: Those
23 statements are included in this,
24 and those were true and accurate

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1 at the time this document was
2 prepared.
3 BY MR. HONIK:
4 Q. Agreed. But more
5 importantly, you agree that it
6 specifically refers to Mylan's
7 compliance -- that's Mylan's words,
8 comply -- with a specific guideline on
9 the limits of genotoxic impurities issued
10 by the European counterpart to the FDA,
11 correct?
12 A. There's a reference to that
13 statement and yes, that was true and
14 accurate at the time the document was
15 prepared.
16 Q. Okay. And by reference, you
17 mean the reliance of compliance that's
18 attested to here by Mylan, correct?
19 A. It refers to a guidance
20 document that we complied with based on
21 the knowledge that we had available at
22 the time the statement was written.
23 Q. Precisely. And your use of
24 the word compliance means that Mylan

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1 followed it and, therefore, complied with
2 the guideline, correct? Is that what you
3 mean?
4 A. I would say that we strive
5 to follow all guidances that are
6 available when we're preparing regulatory
7 submission.
8 Q. That's helpful to know.
9 A. When we file regulatory
10 documents, we strive to comply with the
11 regulations or requirements that are in
12 place.
13 Q. Let me ask you something.
14 Who at Mylan would have
15 written the language that we're looking
16 at together?
17 A. I don't know.
18 Q. Well, what department or
19 departments, plural, collaborate to
20 produce the DMF and file it on behalf of
21 Mylan?
22 A. This would have been a
23 document that came out of the API
24 regulatory science team that prepared the

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1 drug master file for submission.
2 Q. And do they rely upon Mylan
3 scientists for some of the contents of
4 that submission?
5 A. This is a scientific
6 document, so I would say yes in general.
7 Q. And specifically and
8 undoubtedly, the API team that prepared
9 and submitted this on Mylan's behalf,
10 relied upon the work of Matrix that we've
11 looked at in the two previous exhibits,
12 did it not?
13 MR. TRISCHLER: Objection to
14 form. Objection. Calls for
15 speculation.
16 THE WITNESS: Could you
17 repeat that question?
18 BY MR. HONIK:
19 Q. Sure. I'll restate it.
20 It seems plain to me, and
21 you correct me if I'm wrong, Mr. Talton,
22 that the folks that you've now described
23 to me at Mylan, that worked to prepare
24 this DMF submission on behalf of Mylan,

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1 relying as they have, according to your
2 testimony, on science, had to have relied
3 to some extent or another on the Matrix
4 work that we looked at in the two
5 previous development reports, did it not?
6 MR. TRISCHLER: Same
7 objection.
8 THE WITNESS: It's not
9 possible to answer that question
10 because I'm not involved or have
11 knowledge of how they prepared
12 their documents. And I'm not
13 familiar with their practices. So
14 I can't comment on that
15 specifically.
16 BY MR. HONIK:
17 Q. Do you have any doubt that
18 the valsartan development report that we
19 addressed together and you acknowledged,
20 was a detailed development report that
21 reflected the manufacturing processes
22 including that for recovered solvent,
23 informed the development of the DMF and
24 its submission on Mylan's behalf, have

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1 you any doubt of that?
2 MR. TRISCHLER: Objection to
3 the form.
4 Objection to the extent that
5 it calls for speculation.
6 Objection. Asked and
7 answered.
8 THE WITNESS: I'm not
9 familiar with the practice, the
10 documentation practices that
11 Matrix had at the time these
12 documents were prepared.
13 So I can't answer your
14 question specifically.
15 BY MR. HONIK:
16 Q. Well, you were designated on
17 Topic 35 which is Mylan's filings with
18 regulatory authorities including the FDA
19 regarding manufacturing process changes
20 for Mylan's valsartan API drug master
21 filings.
22 Are you aware of that?
23 A. Yeah.
24 Q. And are you telling me that

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1 in your preparations, you didn't conclude
2 that the development reports that we
3 looked at from Mylan's own lab was not
4 apart of the DMF filing?
5 A. I already testified I did
6 not review the drug master file in
7 preparation for today's deposition.
8 Q. Right. You didn't review
9 the DMFs at all, right?
10 MR. TRISCHLER: Ruben, you
11 didn't give him a chance to finish
12 his answer. I'd like to have him
13 have an opportunity --
14 BY MR. HONIK:
15 Q. I just wanted to get an
16 answer. Finish your answer.
17 A. It's the same answer I've
18 given multiple times now.
19 I'm not familiar with the
20 documentation practices used at Matrix at
21 the time that they prepared these drug
22 master files.
23 You're asking me questions
24 about what documents were relied upon. I

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1 can't answer those because I'm not
2 familiar with those practices. So I
3 would only be speculating if I tried to
4 answer them. And you don't think it's
5 appropriate to do that.
6 Q. I'm not sure it would call
7 for speculation, but I take your point.
8 And here is my question:
9 How is it that you are the
10 designee with your experience, sir,
11 recognizing that you were going to be
12 asked about Mylan's filings, including
13 the DMF, and you didn't review the DMF at
14 all? How is that possible?
15 MR. TRISCHLER: Objection.
16 Asked and answered.
17 Argumentative.
18 THE WITNESS: I am aware
19 that a drug master file was filed,
20 and I'm here to testify to that
21 effect.
22 I've also shared with you,
23 as an applicant of an ANDA in the
24 U.S. market how we interact with

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1 that DMF holder.
2 I'm prepared to talk about
3 that.
4 BY MR. HONIK:
5 Q. Okay. Can you tell me who
6 at Mylan or Viatris today could answer my
7 questions about how the drug master
8 filings were prepared, what went into
9 them and who was collaborated with to
10 prepare and submit them? Who would I
11 ask, if not you?
12 A. You would have to speak to
13 the API regulatory science team that
14 actually prepares the DMF.
15 Q. Okay. And do you know the
16 identity of the persons who would have
17 been responsible at that office, the API
18 regulatory people? Who would that be?
19 A. I don't know who
20 specifically. My leader on that team is
21 Imtiyaz Basade. But I don't know who on
22 his team would have prepared the
23 submission.
24 Q. What's the name of the

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1 individual you identified?
2 A. Imtiyaz Basade.
3 Q. Basade? B-A-S-A-D-E?
4 A. Yes.
5 Q. And when you referred --
6 it's a him, right?
7 A. Yes.
8 Q. When you referred to him as
9 being on your team, was he on your team
10 in 2013 when the DMF was finalized and
11 submitted on Mylan's behalf?
12 A. He would have been part of
13 the Matrix -- legacy Matrix and Mylan
14 team. But in 2013, I was in a North
15 America role, I believe.
16 Q. Okay.
17 A. So it wasn't a direct report
18 back then.
19 Q. I understand. But you're
20 saying that he did the work with his
21 team. But the submission was done to the
22 U.S. FDA, correct?
23 A. Through him, through that
24 team. Not through me.

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1 Q. Okay. And who vets it?
2 Where does it go after Basade and his
3 team works on it? How does that work?
4 A. Well, we've already talked
5 about that earlier today, but they
6 prepare the drug master file, and then
7 because they are a foreign facility, they
8 utilize a U.S. agent in order to send
9 that into FDA.
10 Q. So does it undergo review at
11 any point and at any place after Basade
12 finishes with it?
13 A. It comes as a deliverable
14 from him for submission.
15 Q. It comes as a deliverable
16 for whom as a submission?
17 A. To the U.S. agent.
18 Q. Okay. And who does that
19 agent work for?
20 A. I don't recall who was in
21 place in 2013. They had a U.S. agent
22 that was a third-party vendor. We
23 established an internal U.S. agent,
24 probably about five years ago.

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1 Q. And that's -- I have his
2 name. I've seen it a million times.
3 Plastina something like that?
4 A. Michael Plastina, right.
5 Q. Plastina. And if in fact,
6 it was Mr. Plastina, for whom did he work
7 at the time?
8 A. He was part of the North
9 America regulatory affairs team. So they
10 would have reported into the North
11 America head at that time.
12 Q. So let's assume in 2013 when
13 this DMF that we're looking at together,
14 Snider-19, the part that we're looking at
15 in this exhibit, was created by the
16 Basade team and delivered to
17 Mr. Plastina.
18 Let's assume Plastina was in
19 place in 2013. Who -- when Plastina gets
20 it, what does he do with it?
21 MR. TRISCHLER: Objection to
22 form, because it assumes facts not
23 in evidence.
24 I think the witness already

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1 testified that he wasn't in place
2 at that time.
3 MR. HONIK: Please don't --
4 look, I've been restrained in
5 asking you not to speak an
6 objection. Don't do that, please,
7 Clem.
8 BY MR. HONIK:
9 Q. Can you answer my question,
10 sir?
11 MR. TRISCHLER: I'm just
12 stating the basis for the
13 objection, Ruben, because the
14 witness answered.
15 MR. HONIK: You're doing a
16 great deal more -- excuse me.
17 You're doing a great deal
18 more than stating the basis. You
19 don't need to do that,
20 respectfully. Stop.
21 BY MR. HONIK:
22 Q. Can you answer the pending
23 question, sir?
24 A. Maybe you could repeat it.

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1 I don't recall --
2 Q. It's a simple question.
3 After Basade's team prepares
4 the DMF, according to you, and it gets
5 sent to the agent, what does Plastina do
6 with it assuming he was the one to
7 receive it on Mylan's behalf?
8 MR. TRISCHLER: Objection to
9 the form.
10 THE WITNESS: The U.S. agent
11 responsibilities are not
12 extensive. They're primarily to
13 serve as a contact person for the
14 U.S. FDA in case there's questions
15 or follow-up.
16 He would most likely sign
17 the cover letter for the
18 submission and then transmit it
19 electronically to the health
20 authority.
21 BY MR. HONIK:
22 Q. Okay. So am I correct based
23 on your description that after Basade's
24 team at API prepares the DMF with its

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1 scientific inputs, that there's no
2 substantive review after it leaves his
3 hand and his team's hand?
4 A. Yeah, it's delivered to the
5 U.S. agent as a complete document ready
6 for submission.
7 Q. And who -- before it reaches
8 Plastina's hands, apart from the Basade
9 team, as you've already described, if
10 anyone looks at it or formats it or does
11 anything with it?
12 A. I'm not familiar with how
13 the preparation of the DMF occurs or who
14 is involved in the review process. All I
15 can tell you is it comes to the U.S.
16 agent as a complete deliverable for
17 transmission to FDA.
18 Q. And suffice it to say,
19 despite being designated on Topic 35,
20 which involves the DMF, you did nothing
21 before today to learn how this particular
22 DMF was prepared, who prepared it, and
23 what inputs from Mylan divisions were
24 incorporated, correct?

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1 MR. TRISCHLER: Objection to
2 form.
3 THE WITNESS: I've already
4 explained to you that the API drug
5 master files, which team prepares
6 it, who manages the team and how
7 the U.S. agency relationship
8 works, how they communicate with
9 the FDA. I've described all that
10 to you.
11 BY MR. HONIK:
12 Q. I know you have. But my
13 question is, inasmuch as you didn't look
14 at the DMF itself, you're also unable to
15 tell me who provided inputs in its
16 creation, correct?
17 MR. TRISCHLER: Objection.
18 Misstates testimony.
19 THE WITNESS: It's a
20 deliverable from that regulatory
21 science team.
22 BY MR. HONIK:
23 Q. You can't tell me how it was
24 put together though, right?

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1 MR. TRISCHLER: Objection to
2 form. Asked and answered.
3 THE WITNESS: The drug
4 master file is prepared by that
5 team and delivered to the U.S.
6 agent for submission as a complete
7 and ready-to-file submission.
8 BY MR. HONIK:
9 Q. But in this specific
10 instance, the valsartan DMF that we
11 looked at in Snider-19, which was
12 prepared and submitted by Mylan in 2013,
13 you have no knowledge today that you can
14 offer about its specific contents, do
15 you?
16 MR. TRISCHLER: Objection to
17 form. Asked and answered.
18 THE WITNESS: I have not
19 reviewed the drug master file in
20 detail before today.
21 I can tell you what a DMF is
22 and how it's used in connection
23 with filing an ANDA, which I have
24 described.

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1 BY MR. HONIK:
2 Q. Are you capable of telling
3 me why in Snider Exhibit 19 Mylan stated
4 that it complied with the guideline on
5 the limits of genotoxic impurities, an
6 EMEA document from 2006?
7 MR. TRISCHLER: Objection.
8 Beyond the scope.
9 THE WITNESS: I already
10 stated that based on the
11 information available at that
12 time, that was a true and accurate
13 statement.
14 BY MR. HONIK:
15 Q. I know it's true and
16 accurate. My question is, do you know
17 and can you tell me why that statement of
18 compliance and the choice to refer
19 specifically to that document, was put in
20 the DMF on behalf of Mylan?
21 MR. TRISCHLER: Objection.
22 Beyond the scope.
23 THE WITNESS: I've already
24 previously described that it is

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<p>1 our regular practice to comply and</p> <p>2 meet all the regulatory guidance</p> <p>3 and requirements that are in place</p> <p>4 at the time of filing.</p> <p>5 So that document was</p> <p>6 referred to because we were</p> <p>7 indicating that we were in</p> <p>8 compliance with that, just as we</p> <p>9 are with all guidances or</p> <p>10 regulations.</p> <p>11 We strive to meet the health</p> <p>12 authorities' expectations in every</p> <p>13 case.</p> <p>14 BY MR. HONIK:</p> <p>15 Q. When your regulatory affairs</p> <p>16 unit has a submission to U.S. FDA or any</p> <p>17 health authority around the globe, are</p> <p>18 you required to be truthful and honest in</p> <p>19 the submissions and the statements of</p> <p>20 compliance that you make in those</p> <p>21 documents?</p> <p>22 A. Yes.</p> <p>23 Q. And would that be equally</p> <p>24 true for a submission of a DMF?</p>	<p>1 limits of genotoxic impurities issued by</p> <p>2 the EMEA, the European counterpart to the</p> <p>3 FDA in 2006 that's specifically referred</p> <p>4 to in Snider-19 that Mylan claims</p> <p>5 compliance with?</p> <p>6 A. Just give me a second to</p> <p>7 crosscheck the references.</p> <p>8 Q. Yes, sir.</p> <p>9 A. Yes. It appears to be the</p> <p>10 reference that was made in the previous</p> <p>11 exhibit.</p> <p>12 Q. Have you ever seen Exhibit 4</p> <p>13 before, the EMEA document?</p> <p>14 A. I don't recall reviewing</p> <p>15 this before, no.</p> <p>16 Q. Do you know whether anyone</p> <p>17 in your regulatory affairs department</p> <p>18 routinely compiles guidelines like the</p> <p>19 one in Exhibit 4?</p> <p>20 A. We don't have a repository</p> <p>21 of guidelines that are in place.</p> <p>22 As I mentioned before, this</p> <p>23 is why we're structured to have regional</p> <p>24 leaders across the globe who are</p>
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<p>1 A. Yes. We strive to provide</p> <p>2 accurate information that is compliant</p> <p>3 with the regulations and guidance</p> <p>4 documents that are in place at the time</p> <p>5 of the filing.</p> <p>6 Q. Thank you. Can you place</p> <p>7 Tab 4 in front of you.</p> <p>8 MR. HONIK: And believe</p> <p>9 we're going to call this -- to is</p> <p>10 it just Exhibit 4 that we're up to</p> <p>11 or five?</p> <p>12 MR. DAVIS: We are on</p> <p>13 Exhibit 4. Tab 4 will be</p> <p>14 Exhibit 4.</p> <p>15 MR. HONIK: Thank you.</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 PL-Talton-4.)</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Sir, do you have Exhibit 4</p> <p>21 in front of you?</p> <p>22 A. Yes, I do.</p> <p>23 Q. Can you confirm for the</p> <p>24 record this is the guideline on the</p>	<p>1 responsible for monitoring the local and</p> <p>2 regional requirements.</p> <p>3 And as I previously stated,</p> <p>4 it's our practice to strive to meet all</p> <p>5 those requirements that are in place at</p> <p>6 the time that we make our filing.</p> <p>7 Q. Right. And it's true that</p> <p>8 Mylan has had for many years a regional</p> <p>9 department that seeks to comply with the</p> <p>10 European Medicines Agency, correct?</p> <p>11 A. We have a European regional</p> <p>12 team, yes, if that's your question.</p> <p>13 Q. So even today, if you were</p> <p>14 sitting at your office in Morgantown, you</p> <p>15 could call up or communicate with one of</p> <p>16 your European team members and ask them</p> <p>17 for any EMEA guidelines that ever existed</p> <p>18 on the topic such as genotoxic impurity,</p> <p>19 couldn't you?</p> <p>20 A. I mean, I could make an</p> <p>21 inquiry if I wanted to have access to</p> <p>22 something or I could also be resourceful</p> <p>23 and look it up myself.</p> <p>24 Q. Correct. And that's the</p>

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1 very point I'm making is that you or
2 someone at your direction, either in the
3 global office of regulatory affairs or in
4 the team that you oversee in interacting
5 with Europe, have access to Exhibit 4,
6 correct?
7 A. If this is -- if this is a
8 public and current guidance, then it
9 would be made available to anyone that
10 sought it.
11 Q. Well, in fact it's not
12 current. If you look at Page 1 of
13 Exhibit 4, it says, "This document was
14 valid from 1 January 2007 to 31 January
15 2018. And it's since been superseded."
16 Do you see that?
17 MR. TRISCHLER: Objection to
18 form.
19 THE WITNESS: Yes, I see
20 that statement.
21 BY MR. HONIK:
22 Q. And all that means is that
23 this was a valid guideline from 2007 to
24 2018 during the months and days

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1 indicated, right?
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: That would
5 be -- that appears to be the
6 effective date of the guidance,
7 but as I previously testified,
8 guidance and regulations continue
9 to evolve and change.
10 So it's not unusual for a
11 guidance document to go through
12 updates and versioning --
13 BY MR. HONIK:
14 Q. No question?
15 A. -- over time.
16 Q. No question.
17 But specifically, in
18 Snider-19, Mylan said that it complied as
19 of the DMF submission in 2013 with this
20 very guidance, right?
21 A. That's what's stated in that
22 document, and that was true and accurate
23 at the time that it was written.
24 Q. Correct. This guidance,

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1 which was in force and effect in 2013, is
2 the same guidance that's cited in the
3 2013 Mylan DMF submission, correct?
4 A. I've already crosschecked
5 the references and confirmed it. They
6 are referencing the same document.
7 Q. And the guideline itself is
8 headed or titled "'Guideline on the
9 Limits of Genotoxic Impurities," correct?
10 A. That's what's stated on the
11 document.
12 Q. And this was prepared by the
13 European counterpart to the FDA. And
14 specifically it's committee for medicinal
15 products for human use, correct?
16 A. That's on the cover page.
17 Q. And if you turn with me
18 Mr. Talton to Page 6 of 8, I want to
19 direct your attention to a few sections
20 there.
21 A. Okay. I'm on Page 6.
22 Q. The second paragraph that
23 begins with the words, "Some structural
24 groups."

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1 Do you see that?
2 A. Yes.
3 Q. Have you ever seen that
4 reference before, and in particular to a
5 published medical article by Cheeseman in
6 1999 and Kroes in 2004? Have you ever
7 seen that before?
8 MR. TRISCHLER: Objection.
9 Beyond the scope.
10 THE WITNESS: No, I'm not
11 familiar with that literature
12 article.
13 BY MR. HONIK:
14 Q. This section of the
15 guideline, which Mylan claims to have
16 complied with says, "Some structural
17 groups were identified to be of such high
18 potency that intakes even below the TTC
19 would be associated with a high
20 probability of a significant carcinogenic
21 risk."
22 And then it cites the two
23 articles.
24 Do you see that?

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1 A. Yeah.
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: Sorry.
5 BY MR. HONIK:
6 Q. Do you see the next sentence
7 which reads, and I quote: "This group of
8 high potency genotoxic carcinogens
9 comprises aflatoxin-like-, N-nitroso-,
10 and azoxy-compounds that have to be
11 excluded from the TTC approach."
12 Did I read that correctly?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: That's what it
16 states on this document.
17 BY MR. HONIK:
18 Q. And among the listed
19 carcinogens, genotoxic carcinogens of
20 high potency and concern in this
21 guideline are n-nitrosos.
22 Do you see that?
23 MR. TRISCHLER: Objection to
24 form.

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1 THE WITNESS: Yes, I see
2 reference to n-nitroso.
3 BY MR. HONIK:
4 Q. And that refers to
5 nitrosamines, correct?
6 MR. TRISCHLER: Objection to
7 form.
8 THE WITNESS: I can make
9 that assumption.
10 BY MR. HONIK:
11 Q. And you've already told me
12 that both NDEA and NDMA were the
13 nitrosamines of concern that were the
14 impurities found to be in valsartan. You
15 told me that, right?
16 MR. TRISCHLER: Objection to
17 form.
18 THE WITNESS: Based on the
19 investigation and the feedback
20 from the health authorities, those
21 were the two nitrosamine compounds
22 identified of concern.
23 BY MR. HONIK:
24 Q. Based on Mylan's own root

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1 cause analysis, correct?
2 MR. TRISCHLER: Objection.
3 Asked and answered.
4 THE WITNESS: Based on --
5 based on a conclusion of the
6 investigation we had concluded
7 that those impurities may be
8 present.
9 BY MR. HONIK:
10 Q. And the "we" in your
11 statement, the we in your answers, the
12 "we" is Mylan, right?
13 A. Yes.
14 Q. And this 2006 guideline
15 which Mylan claims to have complied with,
16 identifies specifically nitrosamines as
17 one of a number of genotoxic carcinogens
18 of concern in this guideline on limiting
19 such impurities, correct?
20 MR. TRISCHLER: Objection to
21 form.
22 THE WITNESS: There is a
23 reference to the compounds in
24 those documents.

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1 BY MR. HONIK:
2 Q. And this document is a
3 guideline, correct?
4 MR. TRISCHLER: Objection to
5 form. Beyond the scope.
6 THE WITNESS: It's labeled
7 guideline.
8 BY MR. HONIK:
9 Q. And you've already told me
10 numerous times that Mylan, through its
11 regulatory affairs efforts, which you
12 lead globally, adhere to guidelines as
13 best and as closely as you can, correct?
14 MR. TRISCHLER: Objection to
15 form. Asked and answered.
16 THE WITNESS: As I mentioned
17 before, at the time that we make
18 our filings, we take into
19 consideration all guidelines and
20 regulations and we strive to meet
21 those health authority
22 expectations.
23 BY MR. HONIK:
24 Q. Understood. But very

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1 specifically in Snider-19, we saw that
2 Mylan specifically cited compliance with
3 this guideline that we're now looking at,
4 correct?
5 MR. TRISCHLER: Objection.
6 Asked and answered a half dozen
7 times.
8 Go ahead.
9 THE WITNESS: Yes. We
10 crosschecked our reference to the
11 documents and Snider-19 is the
12 same as the doc -- as this
13 exhibit.
14 BY MR. HONIK:
15 Q. And if you turn --
16 A. And as I previously
17 testified, that was a true and accurate
18 statement at the time it was written
19 based on the information we had
20 available.
21 Q. I accept that.
22 So if you turn to the
23 previous page in Exhibit 4, namely Page 5
24 of 8, do you see the Section 5.2.1,

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1 Pharmaceutical Assessment?
2 A. Yes.
3 Q. The prefatory sentence says,
4 "A specific discussion as part of the
5 overall discussion on impurities should
6 be provided in the application with
7 regard to impurities with potential
8 genotoxicity."
9 Did I read that correctly?
10 MR. TRISCHLER: Objection to
11 form.
12 THE WITNESS: That's what
13 the sentence -- sentence states.
14 BY MR. HONIK:
15 Q. And in connection with
16 Mylan's submission of its DMF for
17 valsartan, that's the application that's
18 referenced in that prefatory language,
19 right?
20 MR. TRISCHLER: Objection.
21 Asked and answered.
22 THE WITNESS: I'm sorry,
23 what?
24 Could you ask that again?

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1 BY MR. HONIK:
2 Q. Sure.
3 What this sentence implies
4 is that when a pharmaceutical company is
5 making an assessment and a submission and
6 an application, you've got to concern
7 yourself with impurities with potential
8 genotoxicity, right?
9 MR. TRISCHLER: Objection.
10 Beyond the scope.
11 THE WITNESS: That's a
12 typical element within any drug
13 master file in any ANDA, yes.
14 BY MR. HONIK:
15 Q. Agreed. And if you look
16 with me in the next paragraph, the second
17 sentence, it reads and I quote, "The
18 applicant, like Mylan in its DMF, should
19 highlight within the chemical process and
20 impurity profile of active substance all
21 chemical substances used as reagents or
22 present as intermediates or side products
23 known as genotoxic and/or carcinogenic,
24 e.g., alkylating agents."

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1 Did I read that correctly?
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: That's the
5 sentence in this document.
6 BY MR. HONIK:
7 Q. And the plain meaning of
8 that is that in the case of Mylan and its
9 DMF application, it's supposed to
10 identify, among other things, alkylating
11 agents that have a propensity for
12 genotoxic or carcinogenic
13 characteristics, correct?
14 MR. TRISCHLER: Objection to
15 form. Beyond the scope.
16 THE WITNESS: That sentence
17 is contained within this document.
18 BY MR. HONIK:
19 Q. Okay. And it says, "More
20 generally, reacting substances and
21 substances which show 'alerting
22 structure' in terms of genotoxicity which
23 are not shared with the active substance
24 should be considered" -- and then there's

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1 a cite -- and it concludes in that
2 paragraph with, "Potential alternatives
3 which do not lead to genotoxic residues
4 in the final product should be used if
5 available."
6 Did I read that correctly?
7 MR. TRISCHLER: Objection to
8 form.
9 THE WITNESS: That's what
10 the paragraph states.
11 BY MR. HONIK:
12 Q. And do you understand the
13 language that we just -- I just read and
14 we looked at together, is guiding the
15 applicant, in this case, Mylan, where
16 it's possible to remove a genotoxic agent
17 or one capable of a genotoxic or
18 carcinogenic characteristic, to remove it
19 in favor of an alternative process.
20 Do you understand that?
21 A. My -- my interpretation of
22 the document is just saying if there is
23 an alternative it should be considered,
24 if you have knowledge that you have the

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1 potential to form such an impurity.
2 Q. Exactly. In plain English,
3 it's suggesting the obvious, which is if
4 there is a way to manufacture the drug
5 without a carcinogenic potential, you
6 should do so, correct?
7 MR. TRISCHLER: Objection.
8 Beyond the scope.
9 THE WITNESS: A manufacturer
10 would not normally try to
11 introduce a process that would --
12 that would intentionally produce
13 these toxic impurities.
14 BY MR. HONIK:
15 Q. Absolutely. And where
16 there's an alternative, where you can
17 more readily guarantee that you are not
18 going to have a carcinogenic reaction,
19 then that's what you do, right?
20 A. This guideline is saying if
21 you have knowledge that your process may
22 produce such an impurity, then you should
23 consider an alternative to that. That's
24 the spirit of the guidance as I interpret

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1 it.
2 Q. That's right. In order to
3 have an alternative, you have to have
4 knowledge of it, correct?
5 A. Yes, you have to have
6 knowledge that your process produced such
7 an impurity.
8 Q. Right. So let's sort of
9 bring it home to the valsartan process.
10 What this is implying is
11 that if you can make valsartan without
12 introducing a carcinogen, you should do
13 it that way, instead of using a process
14 or a material or ingredient or encourage
15 a reaction that could produce a
16 carcinogen, correct?
17 MR. TRISCHLER: Objection to
18 the form. Objection, beyond the
19 scope.
20 THE WITNESS: An applicant
21 wouldn't introduce an impurity
22 yet, if they have knowledge that
23 they are introducing it.
24 BY MR. HONIK:

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1 Q. Okay. And you told me
2 earlier in your testimony this morning,
3 Mr. Talton, that you were aware of the
4 process code VAA?
5 A. Yes.
6 Q. And you know, don't you,
7 even though you didn't look at it, you
8 know from a regulatory standpoint, the
9 DMF for the VAA process, which is a
10 valsartan code, was submitted to the U.S.
11 regulators in November of 2017, right?
12 A. I don't remember the -- I
13 don't remember the specific date. But
14 I'm aware that they had multiple
15 processes within the drug master file.
16 Q. But importantly, you recall
17 that the VAA process in terms of its DMF
18 goes back to 2017, right?
19 A. Yes.
20 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 Q. To be sure. But the
8 specific reason that Mylan employed the
9 VAA and we'll look at this later, in a
10 lot of documents, was to remove any
11 potential for a genotoxic impurity,
12 that's why VAA was developed, to
13 eliminate the triethylamine responsible
14 for causing the NDEA and NDMA and in
15 place of it, using sodium bicarbonate in
16 the recovery process, isn't that right?
17 MR. TRISCHLER: Objection to
18 form. Misstates evidence.
19 Objection to the extent it's
20 beyond the scope.
21 THE WITNESS: I don't know
22 why the VAA process was developed.
23 I don't have that knowledge.
24 BY MR. HONIK:

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1 Q. Okay. Well, maybe we'll
2 look at that together and we'll enlighten
3 you further.
4 But assuming, as I'm asking
5 you to, that the VAA process eliminated
6 the potential for a genotoxic impurity by
7 replacing the ingredients that I just
8 identified in 2017, that was therefore an
9 alternative process to create valsartan,
10 wasn't it?
11 MR. TRISCHLER: Objection to
12 form. Beyond the scope.
13 THE WITNESS: As I
14 previously testified, there was
15 multiple alternatives within the
16 drug master file which is not
17 unusual to have multiple processes
18 that are available for the various
19 markets.
20 BY MR. HONIK:
21 Q. Right. Now you're just
22 repeating yourself.
23 My question is this, sir.
24 If, as -- as it appears, Mylan had, at

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1 its disposal, no later than 2017, a
2 process that would eliminate the
3 potential for a genotoxic impurity, why
4 didn't it employ that alternative in all
5 of its production of valsartan?
6 MR. TRISCHLER: Objection to
7 the argument -- argumentative
8 predicate.
9 There's a lot of repeating
10 going on here today.
11 Objection to the extent it
12 goes beyond the scope of the
13 designation.
14 THE WITNESS: As I
15 previously mentioned, there is
16 multiple processes that can be
17 within a drug master file.
18 At the time the VAA process
19 was developed or put in the DMF,
20 there was no knowledge that --
21 that the current process may have
22 introduced these impurities.
23 So there would have been no
24 compelling reason to switch to a

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1 different process, when your
 2 current process was acceptable.
 3 BY MR. HONIK:
 4 Q. You agree that Mylan,
 5 despite having the VAA DMF approved in
 6 2017, continued to sell in the U.S.
 7 market the VLN and VST codes, right?
 8 MR. TRISCHLER: Objection to
 9 form.
 10 THE WITNESS: I don't recall
 11 the specific timelines around
 12 those processes and when they were
 13 supplied to the U.S. market, so
 14 I'm not going to answer that
 15 question.
 16 BY MR. HONIK:
 17 Q. But you know that there was
 18 a recall of the VLN and VST code
 19 valsartan that occurred in late 2018,
 20 correct?
 21 A. Yes. I'm aware of the
 22 recall.
 23 Q. Why did Mylan continue to
 24 sell VLN and VST valsartan to Americans

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1 after it had at its disposal the VAA
 2 process which was approved in 2017 and
 3 remove the genotoxic potential from the
 4 process?
 5 MR. TRISCHLER: Objection.
 6 Beyond the scope.
 7 THE WITNESS: It was not
 8 until late 2018 that we were aware
 9 of the problem.
 10 BY MR. HONIK:
 11 Q. You see the next paragraph
 12 in this section of the Exhibit 4, it
 13 says, "A justification needs to be
 14 provided that no viable alternative
 15 exists, including alternative routes of
 16 synthesis."
 17 Do you see the use of the
 18 term "routes of synthesis"?
 19 A. Yes.
 20 Q. You told me that's the
 21 manufacturing process, correct?
 22 A. That will be my
 23 interpretation.
 24 Q. And then it says, "Or

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1 formulations, different starting
 2 materials. This might for instance
 3 include cases where the structure, which
 4 is responsible for the genotoxic and/or
 5 carcinogenic potential is equivalent to
 6 that needed in chemical synthesis, for
 7 example, alkylation reactions."
 8 Do you see that?
 9 MR. TRISCHLER: Objection to
 10 form.
 11 THE WITNESS: That's what's
 12 stated in the document.
 13 BY MR. HONIK:
 14 Q. Mylan's own root cause
 15 analysis determined that there was an
 16 alkylation reaction that was responsible
 17 for the presence of the nitrosamine
 18 impurities, right?
 19 MR. TRISCHLER: Objection.
 20 Now you're just repeating
 21 yourself. Objection, asked and
 22 answered.
 23 THE WITNESS: As a -- as a
 24 base of an investigation that

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1 wasn't completed until late 2018,
 2 there was no knowledge that the --
 3 the other process was creating or
 4 giving rise to these impurities.
 5 So there would have been no reason
 6 to change your manufacturing
 7 process.
 8 BY MR. HONIK:
 9 Q. Meaning it was unavoidable,
 10 right?
 11 A. Excuse me?
 12 Q. Do you see the next
 13 paragraph? "If a genotoxic impurity is
 14 considered to be unavoidable in a drug
 15 substance, technical efforts, for example
 16 purification steps, should be undertaken
 17 to reduce the content of the genotoxic
 18 residues in the final product in
 19 compliance with safety needs or to a
 20 level as low as reasonably practicable.
 21 Data on chemical stability of reactive
 22 intermediates, reactants, and other
 23 components should be included in this
 24 assessment."

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1 Did I read that correctly?
2 MR. TRISCHLER: Objection to
3 form.
4 THE WITNESS: That's stated
5 in this document.
6 BY MR. HONIK:
7 Q. In what way did Mylan comply
8 with this directive and guideline, the
9 technical efforts should be undertaken to
10 reduce the content of genotoxic residue
11 in valsartan?
12 MR. TRISCHLER: Objection.
13 Beyond the scope.
14 THE WITNESS: It's not
15 possible for me to answer that.
16 But all I can tell you is
17 once we became aware, based on
18 scientific evidence, we took the
19 appropriate action.
20 BY MR. HONIK:
21 Q. Are you aware that sodium
22 nitrite is mutagenic?
23 MR. TRISCHLER: Objection.
24 Objection. Incomplete

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1 hypothetical. Objection, beyond
2 the scope.
3 THE WITNESS: No.
4 BY MR. HONIK:
5 Q. No, you're not aware?
6 A. No.
7 Q. What did Mylan do to comply
8 with the three paragraphs that we just
9 read in Exhibit 4 in Section 5.2.1,
10 Pharmaceutical Assessment, that led it to
11 claim compliance in its DMF submission to
12 the FDA?
13 MR. TRISCHLER: Objection.
14 Beyond the scope.
15 THE WITNESS: I can't
16 specifically talk about the
17 process development report and the
18 conclusions made.
19 But based on the -- based on
20 when that was written and based on
21 knowledge of the process, that was
22 a true and accurate statement.
23 BY MR. HONIK:
24 Q. Well, I'm not sure how your

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1 answer responds to my question, sir.
2 What I asked you was, in
3 what way did Mylan comply with 5.2.1 of
4 the guideline we're looking at marked
5 Exhibit 4, which it specifically cited
6 compliance with in its DMF application
7 for valsartan?
8 MR. TRISCHLER: Objection to
9 form. Beyond the scope.
10 THE WITNESS: And I did
11 answer your question. Based --
12 when that statement was written,
13 based on the knowledge of the
14 process at that time, it was true
15 and accurate. So they did comply
16 with this section.
17 BY MR. HONIK:
18 Q. Well, it seems to me you're
19 citing a tautology. You're saying there
20 was compliance based on some knowledge at
21 the time.
22 My question is specific. In
23 what specific way was compliance with
24 5.2.1 executed by Mylan?

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1 MR. TRISCHLER: Objection to
2 form.
3 BY MR. HONIK:
4 Q. What did it -- what did it
5 do to determine whether there was an
6 appropriate alternative to introducing
7 genotoxic impurities?
8 MR. TRISCHLER: Objection to
9 the form. Argumentative.
10 Objection. Beyond the scope of
11 the designation.
12 THE WITNESS: That's outside
13 my knowledge. You're asking a
14 question about the development
15 process and I don't have that
16 level of knowledge.
17 MR. HONIK: Would you
18 place what's been --
19 MR. TRISCHLER: Ruben,
20 before you go to another document,
21 it's about 12:45. I would like to
22 give the witness a lunch break if
23 we can.
24 MR. HONIK: Okay. Let me --

<p>Page 222</p> <p>1 let me just evaluate what I have 2 here. 3 All right. This is as good 4 a time as any to take it. How 5 long would you like? 6 MR. TRISCHLER: 45 minutes? 7 MR. HONIK: Sure, that's 8 fine. So we're talking 1:30? 9 MR. TRISCHLER: Sure. 10 THE VIDEOGRAPHER: The time 11 is 12:43 p.m. We are going off 12 the record. 13 - - - 14 (Whereupon, a luncheon 15 recess was taken.) 16 - - - 17 THE VIDEOGRAPHER: The time 18 is now 1:31 p.m. Back on the 19 record. 20 BY MR. HONIK: 21 Q. Mr. Talton, you ready to 22 proceed? 23 A. Yes. 24 Q. Okay, good.</p> <p>Page 223</p> <p>1 Before we broke for lunch, 2 you may recall, we were talking about 3 whether or not sodium nitrite was 4 recognized by you as a mutagenic, and I 5 thought you told me you didn't know, 6 right? 7 A. That's correct. 8 Q. Inasmuch as you're a 9 designee of Mylan, do you know whether 10 Mylan is or was ever aware that sodium 11 nitrite is a mutagenic? 12 MR. TRISCHLER: Objection to 13 the extent it's beyond the scope 14 of the designation. 15 MR. HONIK: May I inquire -- 16 I'm having this continued 17 interruption. 18 In what way do you believe 19 that Topic 35, which pertains to 20 Mylan's filings, including its 21 drug master files, and I accept 22 that this particular witness 23 that's been proffered hasn't even 24 looked at the DMF. But to the</p>	<p>Page 224</p> <p>1 extent that there are processes, 2 agents, process -- chemical 3 processes that are reflected in 4 the DMFs, and to the extent one or 5 more of them are mutagenic, how is 6 this not within the topic? 7 Just tell me and I'll try to 8 correct my questioning. 9 MR. TRISCHLER: He's not 10 been designated to talk -- the 11 question that you just asked, 12 Ruben, was Mylan's opinion on 13 whether a different compound was 14 mutagenic. He's not -- 15 MR. HONIK: No, I haven't 16 asked any -- I -- 17 MR. TRISCHLER: If you ask 18 me -- if you ask me to clarify, 19 can I have an opportunity, a 20 position, can I have an 21 opportunity to do it? 22 MR. HONIK: Do whatever you 23 want. 24 MR. TRISCHLER: The question</p> <p>Page 225</p> <p>1 was, did Mylan have an opinion as 2 to whether a given compound, I 3 think you said sodium nitrite, is 4 mutagenic. He's not a 5 toxicologist. He's not been 6 designated on those topics. 7 I don't view Question 35 8 relates specifically to 9 communications regarding 10 manufacturing process changes to 11 include a designation of this 12 witness to talk about what 13 compounds are mutagenic or what 14 compounds are not mutagenic. 15 It's far beyond the scope of 16 the designation. You can disagree 17 if you want. 18 I haven't restricted him 19 from answering the question in his 20 personal capacity. But he's 21 certainly not been designated to 22 speak on issues relating to 23 toxicology which I interpret the 24 question to cover.</p>
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1 MR. HONIK: Are you done?
2 MR. TRISCHLER: For the
3 moment.
4 MR. HONIK: Thank you.
5 BY MR. HONIK:
6 Q. Sir, do you have a
7 definition of mutagenic or mutagen?
8 MR. TRISCHLER: Objection.
9 Beyond the scope.
10 THE WITNESS: No. I mean
11 I've heard the terms. There's a
12 classification of different types
13 of impurities. But I don't have
14 personal or innate knowledge of
15 what that means.
16 BY MR. HONIK:
17 Q. So we have been talking
18 though at some considerable length about
19 the representation of compliance that
20 Mylan made in a filing with the FDA in
21 which it claimed compliance with a
22 European FDA guideline.
23 Remember we were talking
24 about that at some considerable length?

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1 A. Yes, I do recall that
2 conversation.
3 Q. And in the plainest English
4 I can think of, the obligation under that
5 guideline was, Number 1, to identify any
6 potentiality for carcinogenicity in the
7 process that is being submitted in an
8 application, correct?
9 MR. TRISCHLER: Objection to
10 form.
11 THE WITNESS: I mean there
12 is a reference in that report
13 to -- to stay in compliance with a
14 European guideline.
15 BY MR. HONIK:
16 Q. And the purpose of it is so
17 that the company like Mylan would
18 identify whether it was dealing with a
19 potential carcinogen and any alternatives
20 to using materials that could produce a
21 carcinogenic effect. Isn't that the
22 whole point of that guideline, sir?
23 MR. TRISCHLER: Objection to
24 the form.

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1 THE WITNESS: And as -- as
2 we talked about before, the
3 science team that prepares the
4 drug master file made that
5 statement which was true and
6 accurate at the time, and I rely
7 upon them to make those
8 statements.
9 I don't have the innate
10 knowledge to -- to challenge that
11 or not believe it.
12 BY MR. HONIK:
13 Q. And that's what we're
14 examining together, that I'm asking you
15 questions about under oath, because Mylan
16 claimed in its 2013 DMF to the FDA, a
17 topic on which you are designated, that
18 there was no carcinogenic potential.
19 Isn't that what it claimed?
20 A. And we have -- and I have
21 stated that --
22 Q. I just want to know if you
23 recognize that that statement was claimed
24 by Mylan.

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1 A. That statement appears in
2 that DMF as being in compliance with the
3 European guidance based on the
4 information that was available when they
5 wrote that statement.
6 Q. And the claim itself is that
7 there was nothing in valsartan that was a
8 carcinogenic impurity or even capable of
9 producing a carcinogenic impurity,
10 correct?
11 MR. TRISCHLER: Objection to
12 form.
13 THE WITNESS: It states
14 compliance with a European
15 guidance document.
16 BY MR. HONIK:
17 Q. And the guidance document
18 requires an applicant like Mylan to
19 identify any carcinogen or carcinogenic
20 potential, correct?
21 MR. TRISCHLER: Objection to
22 form. Objection. Beyond the
23 scope.
24 THE WITNESS: That's the

<p style="text-align: right;">Page 230</p> <p>1 overall subject of the document, 2 but again, it would be up to the 3 scientists to do the necessary 4 work to support that guidance and 5 to make that certification. 6 That's outside the scope of 7 my role. 8 BY MR. HONIK: 9 Q. And do you understand that a 10 mutagen or a mutagenic agent is one that 11 permanently changes genetic material, 12 usually DNA? 13 MR. TRISCHLER: Objection to 14 the form. Objection, beyond the 15 scope. 16 THE WITNESS: I only have a 17 very general understanding of the 18 different types -- there's a 19 variety of impurities that -- that 20 are in all APIs and finished 21 dosage forms, and we're required 22 to establish specifications and 23 qualify those. But I'm not -- I'm 24 not a biology major. I'm not a</p>	<p style="text-align: right;">Page 232</p> <p>1 you do anything to research that? 2 MR. TRISCHLER: Objection to 3 the form. Beyond the scope. 4 THE WITNESS: As I -- as I 5 previously testified, we get 6 source documents from a variety of 7 disciplines. 8 And -- and the drug master 9 files is one of those 10 deliverables. And I rely upon the 11 scientists to make those decisions 12 and claims. That's not something 13 I would typically challenge. 14 BY MR. HONIK: 15 Q. Under the guidelines that we 16 looked at together that Mylan claimed 17 compliance with in its filing of its DMF 18 in 2013 with the FDA, do you agree that 19 if there was a mutagenic agent in the 20 process for API valsartan, that it needed 21 to be disclosed? 22 MR. TRISCHLER: Objection to 23 form. Incomplete hypothetical. 24 Objection. Beyond the scope.</p>
<p style="text-align: right;">Page 231</p> <p>1 toxicologist, so I really don't 2 have any personal knowledge of the 3 mechanisms by which impurities 4 may -- what impact they may have. 5 BY MR. HONIK: 6 Q. Do you understand that -- 7 that mutagens can cause cancer and that, 8 therefore, they are carcinogens? 9 MR. TRISCHLER: Objection to 10 form. Incomplete hypothetical. 11 Objection. Beyond the scope. 12 THE WITNESS: On my personal 13 knowledge, I have that general 14 understanding. But I'm not going 15 to be able to speak in any details 16 of how that happens or how that 17 works. 18 BY MR. HONIK: 19 Q. Did you do anything, 20 whatever, Mr. Talton, to determine 21 whether or not Mylan, the company you've 22 worked for for over 20 years, believed 23 that sodium nitrite, which it used in the 24 valsartan process, was a mutagen? Did</p>	<p style="text-align: right;">Page 233</p> <p>1 THE WITNESS: I mean as part 2 of your -- your submission, if you 3 have knowledge, shouldn't you have 4 to -- you have -- you would be 5 expected to disclose that if you 6 have personal knowledge of 7 something. 8 BY MR. HONIK: 9 Q. Correct. And to translate 10 that into the context in which I'm asking 11 you, if one or another of the scientists 12 at Mylan knew that there was a mutagenic 13 agent in the process that went into the 14 development and manufacture of API for 15 valsartan, it would need to be disclosed 16 and highlighted under the European 17 guideline, right? 18 MR. TRISCHLER: Same 19 objection. 20 THE WITNESS: Again, you're 21 asking me for -- for details 22 around what conclusions the 23 scientists may -- may draw. And I 24 don't have -- I don't have</p>

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1 knowledge of that.
2 BY MR. HONIK:
3 Q. No, sir. I'm not asking you
4 that at all.
5 I'm asking you if it's true
6 that if there is a mutagenic agent, a
7 chemical agent in the valsartan API
8 process that Mylan's own lab people
9 identified, that under the guidance that
10 we looked at, that Mylan claimed
11 compliance with, it would not only need
12 to identify that agent, but highlight it
13 as a potential genotoxic impurity, yes or
14 no?
15 MR. TRISCHLER: Objection to
16 the form. Objection. Incomplete
17 hypothetical. Objection. Beyond
18 the scope.
19 THE WITNESS: They made
20 certification with compliance with
21 that guideline. So based on their
22 understanding and knowledge of the
23 process, that's a certification
24 they made. I rely upon that as a

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1 regulatory affairs professional to
2 be true and accurate.
3 MR. HONIK: Let's pull up a
4 document that we'll mark as
5 Talton, I think we're up to 5, is
6 it?
7 (Document marked for
8 identification as Exhibit
9 PL-Talton-5.)
10 MR. DAVIS: That's right.
11 And I'll share my screen on this
12 one.
13 MR. HONIK: Yeah.
14 BY MR. HONIK:
15 Q. So this hasn't been sent to
16 you, Mr. Talton, so we'll just bring it
17 up on the screen. It's just an e-mail
18 thread.
19 And let me for the record
20 identify what will be marked as Talton-5.
21 This is an e-mail thread from the Unit 3
22 development lab control in India employed
23 by Mylan concerning, among other things,
24 sodium nitrite.

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1 I presume you've never seen
2 this e-mail thread, Mr. Talton?
3 A. I don't recall seeing this
4 one specifically.
5 MR. TRISCHLER: Ruben, can
6 you scroll down so I can get a
7 Bates number, please.
8 MR. HONIK: Sure. You can
9 scroll. But for the record, it's
10 Bates numbers 494035, 36, and 37.
11 MR. TRISCHLER: Thank you.
12 BY MR. HONIK:
13 Q. And it's an exchange
14 between, among others, Prakash Shenvi and
15 Shambhu Shastri. Do you recognize any of
16 those names?
17 A. No, I don't.
18 Q. Okay. If we look at the
19 thread from January 24th -- this is 2015.
20 And -- do you nonetheless recognize this
21 as an internal communication at Mylan?
22 MR. TRISCHLER: Objection to
23 the form.
24 BY MR. HONIK:

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1 Q. You see it refers to
2 valsartan and the steps for processing
3 valsartan. Do you see it?
4 A. Yes, I'm looking at it. I
5 don't see reference to a Mylan e-mail or
6 anything. But I don't recognize any of
7 the names on the distribution list.
8 Q. Well, do you see at the
9 bottom of Page 2 it says PD lab for VAS
10 code? Does that refresh your memory that
11 this is Mylan?
12 Do you see on Page 1 at the
13 top at 4/1/2015 you've got all of these
14 e-mail addresses ending in Mylan.in, do
15 you see that?
16 A. Yes, I see that now. It
17 wasn't on the page that I was looking at
18 previously. But yes, it does look like
19 an internal Mylan communication.
20 Q. Thank you.
21 And if you look with me at
22 Page 2, which is Bates stamped ending in
23 4036, the thread of the e-mail dated
24 January 24, 2015, at 4:17 p.m., there are

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1 five sections in Roman numbering. Under
2 Section II it says in this Mylan internal
3 communication, "In the proposed
4 process" -- and we're talking about
5 valsartan now -- "in the proposed
6 process sodium nitrite is used in
7 Stage II."
8 And you and I both talked
9 about how there are a couple of stages in
10 the manufacturing process.
11 -- "which is mutagenic."
12 Did I read that correctly?
13 A. That's what is stated in
14 this e-mail.
15 Q. Okay. And you don't have
16 any -- any doubt that the process
17 development folks at Mylan were aware, at
18 least as far back as 2015, and possibly
19 earlier, that the answer to my question
20 that you were unable to answer is sodium
21 nitrite is, in fact, mutagenic, correct?
22 MR. TRISCHLER: Objection to
23 form. Objection. Beyond the
24 scope.

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1 THE WITNESS: All I can
2 comment is this person made that
3 statement, but I can't confirm or
4 deny that.
5 BY MR. HONIK:
6 Q. Mm-hmm. And do you agree
7 that if process development employees at
8 Mylan were aware that sodium nitrite
9 which was introduced in the manufacturing
10 process was mutagenic and in turn could
11 be carcinogenic, that under the
12 guidelines you and I have been talking
13 about and that Mylan certified compliance
14 with, it had an obligation to identify
15 sodium nitrite, particularly in the
16 environment in which it was used, as one
17 capable of genotoxic effect. Isn't that
18 right?
19 MR. TRISCHLER: Objection.
20 Asked and answered. Objection.
21 Beyond the scope.
22 THE WITNESS: Yeah, they
23 certified compliance with that
24 guidance, so that's -- that's

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1 based on their internal
2 development and assessment.
3 You know, so I just -- all I
4 can -- all I can interpret is
5 what's here in front of me, and
6 that's a statement they made.
7 BY MR. HONIK:
8 Q. Nobody in the DMF submitted
9 by Mylan that we've looked at thus far
10 identified sodium nitrite or any agents
11 as having a genotoxic capacity, right?
12 MR. TRISCHLER: Objection to
13 form and foundation.
14 THE WITNESS: I don't know.
15 BY MR. HONIK:
16 Q. I've asked you a very simple
17 question.
18 In the materials you and I
19 have looked at thus far, did you see
20 Mylan make a statement in those filings,
21 and you're the designee for the filings,
22 highlighting the fact that sodium nitrite
23 was used and that sodium nitrite is a
24 mutagenic with a genotoxic impurity

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1 potential. Did you see that anywhere?
2 MR. TRISCHLER: Same
3 objection.
4 THE WITNESS: I don't recall
5 seeing a reference to that
6 previously today.
7 BY MR. HONIK:
8 Q. Thank you.
9 MR. HONIK: Let's bring up
10 Tab 3. And I guess we're up to
11 what, 6.
12 (Document marked for
13 identification as Exhibit
14 PL-Talton-6.)
15 BY MR. HONIK:
16 Q. Do you have that in front of
17 you, Mr. Talton?
18 MR. TRISCHLER: No, we're
19 still looking for it.
20 He has it now, Ruben.
21 MR. HONIK: Thank you.
22 BY MR. HONIK:
23 Q. As I stated, this is Tab 3,
24 I think we're up to Exhibit 6, sir.

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1 It is essentially a ten-page
2 document. The first page is just the
3 metadata page that reveals native format
4 information, and then there are nine
5 pages.
6 And you'll see that this is
7 part of the 2013 DMF from Mylan. Do you
8 see it?
9 A. Yeah.
10 Q. And this particular section
11 is 3.2.S.2. Do you see that?
12 A. Yeah.
13 Q. And once again, this
14 pertains to the manufacturing process
15 development that was submitted by Mylan's
16 own process development scientists in
17 support of the DMFs approval by the U.S.
18 FDA, correct?
19 A. Yes, this appears to be a
20 section from that drug master file.
21 Q. Right. And just to be
22 certain about this, you didn't review
23 this either before today, right?
24 A. No.

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1 Q. And you're literally looking
2 at this DMF section for the first time
3 concerning valsartan?
4 A. Yes.
5 Q. If you turn to the last
6 page, the one that is paginated 9. Do
7 you have that in front of you?
8 A. Yes.
9 Q. Do you see in the middle
10 there's a heading marked Risk Assessment?
11 A. Yes.
12 Q. And then there are a number
13 of statements in that statement including
14 the one that begins with the words, "The
15 synthetic process is critically
16 evaluated."
17 Do you see that?
18 A. Yeah.
19 Q. And we talked about this a
20 little bit. But contextually it's
21 important to go back to this.
22 What does the term or
23 concept "critically evaluated" mean in
24 connection with the synthetic process?

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1 MR. TRISCHLER: Objection to
2 form.
3 THE WITNESS: The term "risk
4 assessment"?
5 BY MR. HONIK:
6 Q. Correct.
7 A. I'm sorry, what was your
8 question?
9 Q. Well, the question was,
10 what's the definition of critically
11 evaluated, and I think you answered it.
12 It refers to a risk assessment, right?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: All I can
16 state is what's interpreted here
17 and they describe what they did as
18 part of their assessment.
19 BY MR. HONIK:
20 Q. Right. A critical
21 evaluation is a risk assessment, in this
22 context, for impurities, right?
23 A. Impurities are covered in
24 this subsection, but it's not only

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1 related to impurities.
2 Q. Correct. In this section it
3 is about impurities, correct?
4 A. No. This section talks
5 about product drying temperature. They
6 talk about some of the additions,
7 maintenance, dealt with temperature and
8 impurities. So it's comprehensive.
9 Q. Agreed. The section we're
10 focused on at the moment, however, deals
11 with impurity profile, right?
12 MR. TRISCHLER: Objection to
13 form. I think he's looking at a
14 different section than you are,
15 Ruben.
16 THE WITNESS: I'm on Page 9
17 under Risk Assessment. And he
18 asked me does this section deal
19 with impurities.
20 And based on my look at this
21 section, there is a part of that
22 that is dealing with impurities.
23 But there's also additional risk
24 assessment part of the evaluation,

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1 which includes process parameters,
2 et cetera.
3 BY MR. HONIK:
4 Q. Right. And maybe I didn't
5 make myself clear. I wanted you to look
6 at the sentence that reads as follows:
7 "The synthetic process is
8 critically evaluated for impurity profile
9 and the following impurities were
10 synthesized in R&D."
11 Do you see that sentence?
12 A. Yes.
13 Q. And that section of this
14 heading, Risk Assessment, deals
15 specifically with a statement by Mylan,
16 which it conveyed to the FDA in its DMF
17 filing, of the impurities that were
18 synthesized in its research and
19 development lab, correct?
20 A. It just lists the
21 impurities, that they were -- they were
22 obvious potential impurities and they
23 described them here, those impurities
24 that --

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1 Q. You recognize the three
2 listed impurities as related substance
3 impurities, correct?
4 A. I mean, many times the word
5 related compound, related substance,
6 impurity, those are used interchangeably.
7 So I can't say exclusively I would refer
8 to them as related substance.
9 Q. And you agree that Mylan did
10 not list n-nitrosos or any nitrosamines,
11 correct?
12 A. They don't appear on this
13 page.
14 Q. Okay. And you and I looked
15 at how the guidelines require identifying
16 n-nitrosos or nitrosamines as potential
17 genotoxic impurities, correct?
18 MR. TRISCHLER: Objection to
19 form.
20 THE WITNESS: There was a --
21 there was a compliance statement
22 with respect to that guidance.
23 But this -- my understanding
24 is this would have been true and

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1 accurate at the time that this
2 document was written.
3 BY MR. HONIK:
4 Q. Do you agree that if Mylan
5 either knew or could have known that its
6 valsartan process, and specifically with
7 respect to the treatment of recovered
8 solvents, had the potential for causing a
9 nitrosamine to develop, that it was
10 obligated to reveal it?
11 MR. TRISCHLER: Objection to
12 the form. Objection. Asked and
13 answered. Objection. Beyond the
14 scope of the designation.
15 THE WITNESS: And based on
16 the inquiries from the regulators
17 and our investigations, that was
18 unknown until 2018.
19 BY MR. HONIK:
20 Q. Right. So your answer isn't
21 responsive to my question.
22 My question is this:
23 If Mylan knew, that is, had
24 actual knowledge, or could have known,

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1 that a nitrosamine could be produced in
2 the recovered solvent process, that it
3 had an obligation to reveal it.
4 MR. TRISCHLER: Same
5 objection.
6 THE WITNESS: You're asking
7 a hypothetical.
8 And what I'm telling you is
9 at the time this document was
10 written, there was no knowledge of
11 that, otherwise they would have
12 disclosed it.
13 BY MR. HONIK:
14 Q. I accept that that's your
15 sworn testimony, sir. I accept that.
16 If, on the other hand, Mylan
17 could have known that a nitrosamine was
18 capable of being produced in the
19 recovered solvent process that it itself
20 described in its own internal lab
21 documents, did it have an obligation
22 under the guidelines, as you understand
23 them as head of global regulatory
24 affairs, to reveal it?

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1 MR. TRISCHLER: Objection to
2 the form. Objection. Asked and
3 answered.
4 THE WITNESS: There was no
5 knowledge of that.
6 BY MR. HONIK:
7 Q. Sir, I'm going to continue
8 to ask this question until you give me an
9 answer, other than there was no
10 knowledge.
11 I'm asking you whether --
12 I'm asking you, sir, respectfully to tell
13 me whether if it was knowable by Mylan
14 that the recovered solvent process using
15 the materials that we've been looking at
16 all morning and afternoon was capable of
17 producing the genotoxic impurity that we
18 now know was in there, did it have an
19 obligation to reveal it?
20 MR. TRISCHLER: And I'd ask
21 respectfully that you have the
22 courtesy to do what you said you
23 were going to do at the outset of
24 the deposition, which is to give

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1 the witness an opportunity to
2 finish his answer before you
3 interrupted him.
4 I'll object to the question
5 as being argumentative and asked
6 and answered and beyond the scope.
7 If you can answer it again,
8 go ahead.
9 THE WITNESS: I don't know
10 how to answer the question, other
11 than the way I've answered it
12 every other time it's been asked.
13 There was no knowledge that
14 such an impurity was being formed.
15 If they had that knowledge, they
16 would have disclosed that and
17 wouldn't have certified compliance
18 to the guidance.
19 You're asking a
20 hypothetical. I can't answer a
21 hypothetical.
22 BY MR. HONIK:
23 Q. So you've said that if the
24 knowledge was capable of being known,

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1 that there was an obligation to reveal
2 it, correct?
3 MR. TRISCHLER: Objection to
4 form.
5 THE WITNESS: No, that's not
6 what I said. You misstated --
7 BY MR. HONIK:
8 Q. You said that there was no
9 actual knowledge, but that if it was
10 known -- and that's all I'm getting at.
11 If it was known or knowable, there was an
12 obligation to reveal it, correct?
13 MR. TRISCHLER: Objection.
14 Argumentative. Objection. Asked
15 and answered. Go ahead.
16 THE WITNESS: Based on our
17 investigation it was unknown in
18 2018. So at the time this
19 document was written, there was
20 nothing to disclose other than
21 these impurities listed within
22 this document.
23 BY MR. HONIK:
24 Q. Sir, let's look at -- let's

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1 take a look at previously marked Exhibits
2 Snider-20 and 15. 20 and 15.
3 (Previously marked
4 PL-Snider-15 and PL-Snider-20.)
5 MR. TRISCHLER: I don't seem
6 to have anything marked Snider-20
7 and 15 unless you are looking at
8 different numbers.
9 Can you describe the
10 documents, Ruben, and see if it's
11 the same thing as --
12 MR. HONIK: Let's go off the
13 video record, please.
14 THE VIDEOGRAPHER: The time
15 is 1:58 p.m. Going off the
16 record.
17 (Short break.)
18 THE VIDEOGRAPHER: The time
19 is now 2:02 p.m. Back on the
20 record.
21 BY MR. HONIK:
22 Q. So first, thank you for your
23 patience. The document that I'm going to
24 use has previously been marked as

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1 Snider-20, and I understand you don't
2 have a hardcopy of it in front of you.
3 But there are just certain parts of it
4 that I'll share with you.
5 And for the benefit of the
6 record, the document was produced to us
7 in native format. It's Bates stamped
8 MYLAN-MDL2875-0055 --
9 MR. TRISCHLER: Ruben, we
10 can't hear you on this end.
11 MR. HONIK: You can't hear
12 me right now?
13 MR. TRISCHLER: Now I can.
14 MR. HONIK: All right.
15 MR. TRISCHLER: We didn't
16 hear your question.
17 I said now we can, we
18 couldn't hear the question.
19 MR. HONIK: Okay. I was
20 just simply identifying for the
21 record the document.
22 BY MR. HONIK:
23 Q. Let me start over.
24 The document in question has

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1 actually previously been filed -- or
2 marked -- as Snider Exhibit 15 --
3 MR. DAVIS: Oh, hang on,
4 Ruben, I thought you wanted 20
5 which is what I have up.
6 MR. HONIK: Why don't you do
7 20. 15 is the attachment.
8 MR. DAVIS: So you want --
9 do you want Plaintiff-Snider-20 or
10 15?
11 MR. HONIK: 15, please.
12 MR. DAVIS: Okay. We might
13 have to go off the record again
14 till I find this. I'm sorry.
15 THE VIDEOGRAPHER: The time
16 is 2:04 p.m. Off the record.
17 (Short break.)
18 THE VIDEOGRAPHER: The time
19 is now 2:10 p.m. Back on the
20 record.
21 BY MR. HONIK:
22 Q. Mr. Talton, first thing's
23 first, can you hear me?
24 A. Yes.

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1 MR. HONIK: And, Clem, can
2 you hear me?
3 MR. TRISCHLER: Yes.
4 MR. HONIK: That's a start.
5 BY MR. HONIK:
6 Q. So I apologize for the
7 confusion. I think the confusion lays in
8 the fact that we may or may not have
9 previously marked this document. So at
10 the risk of stepping out of convention
11 we're just going to mark it anew. And
12 we're going to give it -- Exhibit 6, I
13 think, we're up to.
14 MR. HONIK: Is that right,
15 Michelle?
16 MR. DAVIS: Exhibit 7.
17 MR. HONIK: I beg your
18 pardon. Exhibit 7. Talton-7.
19 (Document marked for
20 identification as Exhibit
21 PL-Talton-7.)
22 BY MR. HONIK:
23 Q. And, Mr. Talton, we're going
24 to screen share here. It's a very long

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1 document, in excess of 90 pages. And
2 suffice it to say I'm only going to show
3 you or contextualize for you one or two
4 pages, not to worry about all hundred of
5 them.
6 The first page, as a lot of
7 these documents are, Mr. Talton, describe
8 or reveal the native format. So it tells
9 us what the file name is and its
10 creation, and you can see it's called
11 Valsartan Response to FDA Query, and it's
12 a 2018 pdf.
13 And for the benefit of your
14 counsel more than anyone, it's Bates
15 stamped 00552465.
16 So if we turn to the first
17 page of the document, you'll see,
18 Mr. Talton, it's a letter to Mylan
19 Laboratories Limited care of its agent
20 who you identified by name earlier, and
21 that's Michael Plastina.
22 I think they've got Wyoming
23 instead of West Virginia. But that's
24 where he is in Morgantown.

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1 And you'll see, as I'm sure
2 you've seen in many other instances in
3 your job, it concerns, in this case, the
4 drug master file, the DMF for valsartan,
5 and it contains questions that the FDA is
6 posing to Mylan through its agent Michael
7 Plastina.
8 Do you see this form letter?
9 A. Yes.
10 Q. And you've seen letters like
11 this before, have you not?
12 A. Yes. Getting requests for
13 information from FDA is a very common
14 practice.
15 Q. And among the common
16 practices is to ask for information
17 concerning a company's DMF filing, drug
18 master file, right?
19 A. Yes.
20 Q. And given the date of this
21 letter, in the summer of 2018, I think
22 you can see that, and you will see in a
23 moment more clearly, that it pertained to
24 the FDA's investigation concerning the

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1 recall of sartan drugs. Are you aware of
2 that?
3 A. Yes, I am aware of a recall
4 of valsartan containing products in 2018.
5 Q. Fair enough.
6 So if we turn together,
7 deeper into the document to Page 1 of 14.
8 It's actually paginated that way at the
9 lower right.
10 Okay. So here is 1 of 14.
11 And here is a question that
12 the FDA posed to Mylan in the summer of
13 2018, July.
14 It says, and I quote at
15 Number 1, "The Agency has tested samples
16 from three batches of your API and found
17 they contained NDEA. Based on the
18 information provided in your DMF" --
19 that's what we've been looking at
20 together -- "the components that form
21 NDEA do not seem to be present in your
22 process. We have the following
23 questions/requests:"
24 Do you see that, sir?

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1 MR. TRISCHLER: Just
2 objecting to the form and
3 predicates that I think are not
4 factually accurate.
5 But go ahead.
6 MR. HONIK: I'm at a loss to
7 understand your objection. All I
8 did was the sentence and asked if
9 I read it correctly.
10 MR. TRISCHLER: Okay. We
11 have -- you represented that this
12 was a July 2018 inquiry. I'm
13 looking at the top of the document
14 and it references November 13,
15 2018.
16 Neither I, nor the witness,
17 have had an opportunity to see the
18 whole document, given the nature
19 of how it's being presented,
20 Ruben.
21 And all I'm doing is
22 objecting to the predicate
23 statement that you've made
24 regarding this response letter

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1 having been submitted in June or
2 July.
3 I don't think that's -- that
4 does not appear to be the case.
5 That's the nature of my
6 objection.
7 MR. HONIK: The question is
8 did I read the sentence correctly.
9 MR. TRISCHLER: That wasn't
10 the entire question, but go ahead.
11 BY MR. HONIK:
12 Q. Mr. Talton, the question is
13 to you, not your lawyer. Did I read the
14 sentence correctly?
15 A. Yes.
16 Q. And do you understand the
17 sentence to be an inquiry from the FDA to
18 Mylan, whether it occurred in November or
19 July of 2018, regardless of the date, do
20 you recognize it as a question that the
21 FDA had for Mylan?
22 A. Yes, I recognize it as an
23 inquiry that we received from FDA in
24 November of 2018 asking us to provide a

<p style="text-align: right;">Page 262</p> <p>1 response to this comment.</p> <p>2 Q. And the question they asked</p> <p>3 was, having tested three batches of its</p> <p>4 API and finding NDEA, FDA can't figure</p> <p>5 out where that would have come from, the</p> <p>6 NDEA, based on what Mylan revealed in its</p> <p>7 DMF and could it please provide a</p> <p>8 description of some plausible mechanism</p> <p>9 for how the impurity got in there.</p> <p>10 Isn't that right?</p> <p>11 MR. TRISCHLER: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: Based on this</p> <p>14 statement they are just asking us</p> <p>15 to provide a plausible mechanism</p> <p>16 of how that impurity might be</p> <p>17 found in our drug substance.</p> <p>18 BY MR. HONIK:</p> <p>19 Q. Correct. But contextually</p> <p>20 it said, the FDA said, that they couldn't</p> <p>21 figure it out based on the DMF that Mylan</p> <p>22 had filed with the FDA. Isn't that also</p> <p>23 what it says?</p> <p>24 MR. TRISCHLER: Objection to</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. Correct. Because they</p> <p>2 couldn't figure it out on their own based</p> <p>3 on Mylan's submission of its DMF to the</p> <p>4 federal drug agency, right?</p> <p>5 MR. TRISCHLER: Objection to</p> <p>6 form. Objection. Asked and</p> <p>7 answered.</p> <p>8 THE WITNESS: "Based on the</p> <p>9 information provided in your drug</p> <p>10 master file, the components that</p> <p>11 form NDEA do not seem to be</p> <p>12 present in your process."</p> <p>13 BY MR. HONIK:</p> <p>14 Q. Right.</p> <p>15 A. That's what FDA stated.</p> <p>16 Q. Right. So they are now</p> <p>17 asking Mylan to provide some plausible</p> <p>18 mechanism for why this impurity is being</p> <p>19 found in your drug substance. That's</p> <p>20 what the question is, right?</p> <p>21 A. Yes. They're asking us to</p> <p>22 help them understand how that might</p> <p>23 happen.</p> <p>24 Q. Correct. Because they</p>
<p style="text-align: right;">Page 263</p> <p>1 form.</p> <p>2 THE WITNESS: The comment</p> <p>3 from FDA was based on the</p> <p>4 information provided in the DMF.</p> <p>5 The components that form</p> <p>6 NDEA do not seem to be present in</p> <p>7 your process.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. That's right.</p> <p>10 A. That's what FDA --</p> <p>11 Q. They're saying they couldn't</p> <p>12 figure out, based on what Mylan revealed</p> <p>13 in its DMF, how NDEA could have plausibly</p> <p>14 gotten into the valsartan. Isn't that</p> <p>15 what they were saying?</p> <p>16 MR. TRISCHLER: Objection to</p> <p>17 form. Objection. Asked and</p> <p>18 answered.</p> <p>19 THE WITNESS: Based on the</p> <p>20 comment as written here, they are</p> <p>21 just stating for us to help them</p> <p>22 understand how that might be</p> <p>23 possible.</p> <p>24 BY MR. HONIK:</p>	<p style="text-align: right;">Page 265</p> <p>1 couldn't figure it out based on the DMF,</p> <p>2 right?</p> <p>3 MR. TRISCHLER: Objection to</p> <p>4 form. Objection. Asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: All I can --</p> <p>7 all I can state is what's written</p> <p>8 in the letter from FDA, which I've</p> <p>9 said two times already.</p> <p>10 Based on the information in</p> <p>11 your DMF, the components that form</p> <p>12 do not seem to be present. Help</p> <p>13 us understand this.</p> <p>14 BY MR. HONIK:</p> <p>15 Q. And so as latest, as you</p> <p>16 pointed out, November of 2018, the</p> <p>17 regulatory agency that you interact with</p> <p>18 and that Mylan has an obligation to</p> <p>19 comply with, couldn't understand how NDEA</p> <p>20 got in there and it was asking Mylan to</p> <p>21 describe how it could have happened,</p> <p>22 right?</p> <p>23 A. They are asking us to</p> <p>24 provide a plausible mechanism for why</p>

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1 that impurity might be found in our drug
2 substance.
3 Q. Correct. And it was asking
4 Mylan in November of 2018 that very
5 question, right?
6 A. It appears that this -- that
7 query came in a correspondence dated
8 November 13, 2018.
9 Q. Okay. And the response is
10 below.
11 Did you or someone at your
12 direction in regulatory affairs prepare
13 this response?
14 A. I did not prepare this
15 response. As I previously testified, an
16 inquiry into the drug master file holder
17 would be communicated to the DMF holder
18 and then they would provide the written
19 responses to provide back to what the
20 agent for submission.
21 Q. Okay. Can I unpack that a
22 little bit and understand what you mean?
23 Do you mean to say that
24 Michael Plastina gets the question and

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1 then gives it to someone to answer, is
2 that what you mean?
3 A. I previously described the
4 U.S. agent role for drug master files.
5 So FDA requires you have a U.S. agent if
6 you are a foreign -- if you're located in
7 a foreign country.
8 So Michael would be the
9 recipient of the communication. He in
10 turn would send it or disseminate the
11 information to the API science team who
12 prepares and maintains the drug master
13 file.
14 Q. And the API science team
15 is -- are the Mylan employees in India
16 who are responsible for manufacturing the
17 API; is that correct?
18 A. It's the regulatory science
19 team. So it's the team led by Imtiyaz
20 Basade that I referred to earlier.
21 Q. So you are -- you are the
22 senior manager of the regulatory science
23 team, aren't you?
24 A. The regulatory science teams

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1 do report into me, yes.
2 Q. Okay. So a team that you
3 have managerial responsibility for gets
4 this question and they are the ones that
5 supply the response, correct?
6 A. Yes, the scientists.
7 Q. Okay. And you mentioned one
8 scientist by name, and I apologize to you
9 because I couldn't hear you quite well.
10 Could you tell me the name
11 of the scientist that you named that got
12 this inquiry?
13 A. Well, it would have come --
14 it would have come to the U.S. agent
15 Michael Plastina, and he in turn would
16 have sent it to the DMF team. That team
17 is led by Imtiyaz Basade.
18 Q. Okay. And Basade is a
19 report to you, right?
20 A. He is. As -- as I talked
21 about earlier he has a dual role. He has
22 API science, as well as emerging markets
23 from a regional perspective.
24 Q. Are there any intermediate

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1 reports between Basade and you?
2 A. He has a dual management, so
3 he reports to me as well as to the R&D
4 head.
5 Q. And who is that as of late
6 2018?
7 A. I can't remember.
8 Apologies.
9 Q. Okay. So Plastina gets the
10 question, the letter, sends it to your
11 direct report Basade, and then Basade and
12 any of his underlings undertake to
13 prepare a response. Is that correct so
14 far?
15 A. Well, Imtiyaz who leads the
16 API science team would work with R&D to
17 prepare the response.
18 Q. Okay. And you don't
19 remember either the head of the R&D at
20 the time or anyone that might have worked
21 on this response?
22 A. Not specifically in India,
23 no.
24 Q. Okay. Who in addition to

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1 the R&D team would Basade have worked
2 with?
3 A. I don't know. You'd have to
4 ask Imtiyaz that.
5 Q. And I think you
6 identified -- I don't know if it's a
7 separate team, but I think you referred
8 to a DMF team, didn't you?
9 A. Well, Imtiyaz leads the team
10 that prepares the DMF.
11 Q. I apologize, but I'm having
12 a hard time understanding you. Who --
13 A. From a volume perspective or
14 I'm not being clear in my explanation?
15 Q. Both from a volume
16 perspective and you're saying the proper
17 names quickly, and I apologize, with your
18 accent I'm having trouble making out the
19 name.
20 Who is in charge of the DMF
21 team?
22 A. Imtiyaz Basade.
23 Q. Okay. So Basade heads up
24 the DMF team. And you don't know the

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1 name of the R&D head at the time; is that
2 right?
3 A. He would have worked with
4 the local R&D in India. No, I do not
5 know who that was in 2018.
6 Q. Okay. So procedurally,
7 Basade gets it as the head of DMF who is
8 a direct report of yours, works with the
9 local R&D head and together they prepared
10 the response that we see here in exhibit
11 whatever we're up to, right?
12 A. They will work together to
13 prepare the response, yes.
14 Q. And when that response is
15 finalized, who sees it next?
16 A. Once the submission was
17 finalized it would go back to Michael
18 Plastina to submit to FDA.
19 Q. Okay. Does anybody in
20 global regulatory affairs, that is to say
21 your office, review the response prepared
22 by Basade and any R&D people he consults?
23 A. No.
24 Q. Why is it kept strictly with

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1 the folks at the DMF and local R&D?
2 A. Well, we talked about that
3 earlier today, but a drug master file by
4 nature is a confidential document. And
5 as I mentioned before, this is a separate
6 business. So I won't even see this type
7 of communication because it would go to
8 the U.S. agent, then to the DMF team,
9 back to the agent and then to the FDA.
10 Q. And am I correct --
11 A. We only incorporate -- can I
12 finish? We only incorporate the content
13 of the drug master file through a letter
14 of authorization. We don't actually
15 submit the drug master file in our
16 applications.
17 Q. And is it correct that in
18 preparation for today, and despite the
19 separation that you've now described to
20 me a number of times, you nonetheless
21 didn't look at any of these documents in
22 preparation for your testimony, correct?
23 A. No, I never said that. I
24 said I didn't review the DMF in its

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1 entirety. But communications to and from
2 the agencies I did take a look at.
3 Q. Okay. Did your review
4 include communications to and from the
5 FDA like the document we're looking at?
6 Have you seen this before?
7 A. Yes, in preparation for
8 today's testimony, yes, I reviewed this.
9 Q. Okay. So let me back up a
10 step here.
11 MR. HONIK: So, John, what
12 is the name -- the number of this
13 exhibit?
14 MR. DAVIS: Exhibit 7.
15 BY MR. HONIK:
16 Q. You've seen Exhibit 7 before
17 today?
18 A. Yes.
19 Q. Okay. And you looked at it
20 specifically to prepare for today; is
21 that right?
22 A. Yes.
23 Q. Why did you look at this
24 document to prepare for today?

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1 A. It was my understanding that
2 I was designated to speak on
3 communications with FDA with respect to
4 these filings.
5 This is a communication
6 directly to the FDA.
7 Q. Okay. And when you saw the
8 question here, and you saw the response,
9 did it trigger in you any interest in
10 looking at the DMF which is the subject
11 of the FDA's question?
12 A. No.
13 Q. When you read the question
14 in preparation for today, did you
15 understand that the FDA was unable to
16 determine, by looking at Mylan's DMF,
17 what in the process could have produced
18 the NDEA? Did you understand that when
19 you first read it in preparation for
20 today?
21 MR. TRISCHLER: Objection.
22 Asked and answered.
23 THE WITNESS: We've already
24 been through this. But all I can

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1 tell you is what's -- what's
2 stated here is the FDA asked us to
3 help them understand how that
4 might be possible.
5 BY MR. HONIK:
6 Q. And in the response Mylan
7 says that triethylamine is used as a base
8 in Stage I of the process for valsartan
9 VST. Do you see that?
10 A. Yes.
11 Q. And I think you told me
12 earlier in your sworn testimony that you
13 didn't remember VST as a code for
14 valsartan. Does this refresh your
15 recollection?
16 MR. TRISCHLER: Objection to
17 the form.
18 THE WITNESS: No. I
19 acknowledge that I recognize the
20 VST. It was VDL or some other
21 code that I was not familiar with.
22 BY MR. HONIK:
23 Q. Fair enough.
24 [REDACTED]

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1 [REDACTED]

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1 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 BY MR. HONIK:
2 Q. Well, when you prepared for
3 today, did you see anything that
4 indicated to you that VAA replaced the
5 VST because VAA doesn't produce
6 nitrosamines?
7 A. That was an alternate
8 process that was developed at some point.
9 For what reason, I don't know. I'm not
10 the right person to answer that.
11 But to answer this specific
12 question from FDA, they were putting it
13 in context to explain the differences.
14 Q. Right. You haven't answered
15 my question, sir.
16 My question is, did you see
17 anything in preparation for today which
18 confirmed to you the VAA process did not
19 introduce any nitrosamines into
20 valsartan?
21 MR. TRISCHLER: Objection to
22 form. Vague as to time.
23 THE WITNESS: I mean,
24 following the investigation, I

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1 think there was a determination
2 that that would be the appropriate
3 process to use going forward
4 because it wouldn't give rise to
5 the impurity, based on the
6 conclusion of the investigation.
7 BY MR. HONIK:
8 Q. That's exactly what I asked
9 you, sir.
10 I asked you whether you
11 didn't come to realize by review of
12 documents before today's testimony that
13 the VAA process did not introduce NDEA
14 and that Mylan was going exclusively with
15 that process.
16 You've now confirmed that
17 you were aware of that, correct?
18 A. That was part of the
19 investigation which I have acknowledged
20 that I have reviewed.
21 Q. And that's all I want to
22 establish.
23 Sitting here today, you know
24 that VAA was a process that didn't

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1 introduce NDEA and that's exclusively
2 what Mylan would be using to produce
3 valsartan, correct?
4 MR. TRISCHLER: Objection to
5 form.
6 THE WITNESS: Following the
7 conclusion of the investigation,
8 Mylan did move to the VAA process
9 as a way to remediate the issue.
10 BY MR. HONIK:
11 Q. And the response that we're
12 looking at in Exhibit 7 confirms that
13 that process code, that process
14 manufacturing was available as of
15 November 2017, correct?
16 MR. TRISCHLER: Objection to
17 form.
18 THE WITNESS: This states
19 when the amendment was filed. But
20 that was -- we did not have
21 knowledge at that time there was
22 an issue with the VST process. So
23 that's why you have to look at it
24 in complete context.

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1 BY MR. HONIK:
2 Q. Mylan had an approved DMF as
3 of 2017 for the VAA process code,
4 correct?
5 MR. TRISCHLER: Objection to
6 form.
7 THE WITNESS: Can you repeat
8 that, please?
9 BY MR. HONIK:
10 Q. Mylan had an approved DMF by
11 the United States Food and Drug
12 Administration in 2017 for VAA, which is
13 a process for valsartan that does not
14 introduce NDEA, correct?
15 MR. TRISCHLER: Same
16 objections.
17 THE WITNESS: First of all,
18 I need to clarify, drug master
19 files are not approved. Okay?
20 They are reviewed in context with
21 an applicant's submission.
22 They are never reviewed --
23 they are never approved.
24 BY MR. HONIK:

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1 Q. Okay. Mylan as of 2017 had
2 a fully reviewed DMF by the FDA which
3 sent no rejections, which it can do,
4 right? DMFs can be rejected, correct?
5 A. They can be found deficient,
6 yes.
7 Q. Okay. Have there been any
8 deficiencies to your knowledge as head of
9 regulatory affairs of the 2017 VAA DMF
10 that Mylan filed?
11 A. I'd have to go look in --
12 back and look at the DMF correspondence
13 subsequent to that amendment. I don't --
14 don't know sitting here today.
15 Q. Okay. Sitting here today,
16 you don't know of any, do you?
17 A. Like I said, I'd have to go
18 back and look at the regulatory record in
19 order to answer your question.
20 Q. But suffice it to say, as of
21 2017, Mylan had available to it a process
22 code, that is, a way to manufacture
23 valsartan, that would be free of
24 nitrosamines, correct?

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1 A. There was an alternate
2 process registered, but we also talked
3 about earlier that it is not unusual to
4 have multiple processes within a single
5 DMF because this -- this material was
6 supplied to various markets, including
7 the U.S., but in other markets as well.
8 Q. Why did not -- why did not
9 Mylan reveal the alternate process, which
10 is free of nitrosamines, to the FDA
11 before November 2018?
12 MR. TRISCHLER: Objection to
13 form.
14 THE WITNESS: There was no
15 knowledge -- until the
16 investigation was completed, there
17 was no knowledge there was an
18 issue with the current process.
19 And just because a drug
20 master file contains multiple
21 processes does not mean that you
22 can use it in the manufacture of
23 your finished dosage form.
24 MR. HONIK: Let's take a

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1 look at Tab 6, please.
2 (Document marked for
3 identification as Exhibit
4 PL-Talton-8.)
5 MR. HONIK: We're going to
6 mark that as Talton Exhibit 8.
7 MR. TRISCHLER: I found it.
8 Sorry.
9 BY MR. HONIK:
10 Q. Do you see that this
11 document is also part of the drug master
12 file, again 3.2.S.2.
13 Do you see that?
14 A. Yes.
15 Q. If you can turn to the very
16 first page which is the native format
17 information. You see it's a document
18 generated in June of 2013.
19 Do you see that?
20 A. Yes.
21 Q. If you turn with me to the
22 page that's actually numbered Number 4,
23 lower right-hand corner. This is the
24 part of the drug master file on valsartan

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1 submitted by Mylan that provides the
2 process description.
3 Do you see that?
4 A. Yes.
5 Q. And here it breaks out in a
6 way you weren't able to discern earlier,
7 that F and R are for fresh and recovered.
8 Do you see that?
9 A. Yes. It's clear on this
10 text.
11 Q. Okay. And so you'd agree
12 that when we saw F and R before, that it
13 meant fresh and recovered, right?
14 MR. TRISCHLER: Objection to
15 form.
16 THE WITNESS: I would assume
17 that's what those mean.
18 BY MR. HONIK:
19 [REDACTED]

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1 [REDACTED]

Page 288

1 [REDACTED]

Page 289

1 [REDACTED]

Page 290

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 BY MR. HONIK:
11 Q. Okay. And the guidance that
12 the European FDA counterpart gave Mylan,
13 which Mylan claimed compliance with to
14 the U.S. FDA, specifically says, no
15 matter the agent, no matter the
16 intermediary, no matter what it is, if
17 you're using it in your process to make
18 an API, to make a finished dose, and it
19 has the potential to be a genotoxic
20 impurity, that it has to be identified,
21 and indeed if there is an alternative,
22 you have to use the alternative, didn't
23 we see that together?
24 MR. TRISCHLER: Objection to

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1 the form. Objection. Asked and
2 answered.
3 THE WITNESS: There -- there
4 was no knowledge that there was an
5 issue or concern with the process
6 as registered.
7 BY MR. HONIK:
8 Q. Well, that's a conclusion.
9 I'm not at the conclusion. I'm asking
10 you simply if the guidance requires that
11 if there is a solution, a process,
12 anything, any part of the manufacturing
13 process that has the potential for
14 introducing a genotoxic impurity, that it
15 has to be first identified. And if
16 there's an alternative, to turn to the
17 alternative in place of the genotoxic
18 potential. Isn't that the guideline
19 standard?
20 MR. TRISCHLER: Objection.
21 Asked and answered.
22 THE WITNESS: As I
23 previously testified, there was no
24 requirement to specify how

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1 recovered solvents might be used
2 in a drug master file.
3 For a drug master file in
4 the U.S., you just have to
5 register the specifications by
6 which a solvent must adhere to,
7 prior to use.
8 BY MR. HONIK:
9 Q. But if the recovery process
10 introduces materials, intermediates,
11 agents of any sort that have a genotoxic
12 potential, either known or knowable under
13 the guideline we looked at, that has to
14 be identified, isn't that correct?
15 MR. TRISCHLER: Objection.
16 Asked and answered.
17 THE WITNESS: There was no
18 such knowledge that existed.
19 BY MR. HONIK:
20 Q. Sir, I'm not asking --
21 A. Whether you -- can I
22 complete my sentence, please? Can I
23 complete my answer?
24 Q. I'd rather you not because

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1 you're just repeating yourself.
2 Instead, I want to point out
3 to you that I'm not asking how the
4 guidelines --
5 MR. TRISCHLER: The witness
6 is -- this is -- this is rude.
7 THE WITNESS: There's a
8 fundamental --
9 MR. TRISCHLER: He has a
10 fundamental right to finish his
11 answer. You've told him that, and
12 now you're refusing to permit him
13 to do it. You are complaining
14 about repeating. I could complain
15 about a question being asked 42
16 times in this deposition.
17 MR. HONIK: Let me assure
18 you --
19 MR. TRISCHLER: Let the
20 witness -- let the witness answer
21 the question, please. That's what
22 he's always asked.
23 MR. HONIK: Let me assure
24 you -- let me assure you of

Page 295

1 something. If you want to pause
2 the deposition and get Judge
3 Vanaskie on the line or present to
4 him this video and the last eight
5 or ten questions or any grouping
6 of eight or ten questions, we can
7 do that.
8 But the witness respectfully
9 is not being responsive to my
10 question. And the repetition is
11 not occurring from me for no
12 reason. It's occurring because
13 the witness isn't responding to
14 the pending question.
15 Now, as a point of
16 clarification to Mr. Talton to
17 help him, help all of us, I'm
18 pointing out that I'm not asking
19 how the guideline applies in this
20 case to Mylan.
21 BY MR. HONIK:
22 Q. I'm merely asking if the
23 guideline in your reading, Mr. Talton,
24 doesn't require someone who claims

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1 compliance with the guideline to identify
2 any agent, any intermediary, any part of
3 the process that has a genetic impurity
4 potential to be identified, the answer to
5 which is yes, no, or you don't know?
6 MR. TRISCHLER: Ruben, I
7 don't -- I don't need you to help
8 the witness. I need you to allow
9 the witness to answer the
10 question the question.
11 MR. HONIK: I've reframed --
12 MR. TRISCHLER: I'm
13 responding to --
14 MR. HONIK: I have reframed
15 the question --
16 MR. TRISCHLER: I'm
17 responding to your speech as I'm
18 entitled to.
19 MR. HONIK: I have reframed
20 the question. I don't want you to
21 interrupt. There's a new pending
22 question.
23 If you have an objection,
24 simply state it.

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1 MR. TRISCHLER: I'm
2 objecting that the question has
3 been asked and answered.
4 MR. HONIK: It's noted.
5 BY MR. HONIK:
6 Q. Answer the question,
7 Mr. Talton.
8 A. If one had knowledge of that
9 in that time period, yes, it would need
10 to be disclosed. But we had no knowledge
11 of that type of impurity at that point in
12 time based on the investigation.
13 And the point I wanted to
14 make earlier, which I think is relevant
15 for you to understand with respect to
16 drug master files, when solvents are
17 used, whether they are fresh or
18 recovered, in the U.S. you are required
19 to register those specifications.
20 But whether it's virgin or
21 recycled, you still have to adhere to the
22 same quality standard. I think that's
23 important to know.
24 Q. That's your answer, is that

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1 your complete answer?
2 A. Yes.
3 Q. Thank you.
4 MR. HONIK: Let's bring up
5 Glover previously marked
6 Exhibits 30 and 31, please.
7 (Previously marked
8 PL-Glover-30 and PL-Glover-31.)
9 BY MR. HONIK:
10 Q. Do you have those in front
11 of you, sir?
12 A. Not yet.
13 MR. TRISCHLER: The witness
14 now has those documents, Ruben.
15 BY MR. HONIK:
16 Q. Do you see Glover-30 is an
17 e-mail exchange between Dr. Gomas and
18 Dr. Owens in the first instance,
19 March 20, 2019?
20 A. Yes.
21 Q. And you see the attachments
22 in the upper part of the e-mail thread,
23 refers to a valsartan FDA doc.
24 A. I see reference to that

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1 attachment.
2 Q. And so Glover-31 is that
3 attachment. It was used with Dr. Glover,
4 Mr. Glover.
5 And you see that it pertains
6 to an investigation at Lantech. Do you
7 see that?
8 A. Yes.
9 Q. And there are a series of
10 questions and responses beginning on the
11 first of the two pages that comprise
12 Glover-31.
13 If you turn to the second
14 page. The last of the questions,
15 Number 4, reads: "Were they removed from
16 our DMFs if ever" -- "if they were ever
17 included?"
18 And the response here is,
19 "Since solvent recovery processes are not
20 part of any of our API DMFs, Lantech is
21 not part of any of our DMF submissions."
22 Do you see that?
23 A. Yes.
24 Q. So this is a statement you

Page 300

1 made to me previously, which is
2 confirming that the solvent recovery
3 process, although known to Mylan
4 employees at Matrix, were not made part
5 of any submission of the DMF to the FDA,
6 correct?
7 A. Based on the guidelines in
8 place at the time, there was no
9 requirement to disclose solvent recovery
10 centers.
11 [REDACTED]

Page 301

1 [REDACTED]

Page 302

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 Q. Well, you agree that the FDA
11 wanted to know in 2018, right?
12 A. Wanted to know what?
13 Q. It wanted to know how it was
14 possible based on the DMF submission by
15 Mylan, how NDEA could have gotten in
16 there?
17 MR. TRISCHLER: Objection.
18 Asked and answered.
19 THE WITNESS: They sent us
20 an inquiry and asked us to help
21 them understand how that could
22 have happened.
23 BY MR. HONIK:
24 Q. Correct. And had Mylan

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1 revealed the recovery process earlier,
2 the FDA would have never asked that
3 question because it would have known,
4 correct?
5 MR. TRISCHLER: Objection to
6 form. Calls for speculation.
7 THE WITNESS: That's not
8 possible to answer that question.
9 As I mentioned before, when
10 all this -- when this issue arose,
11 it resulted in an investigation.
12 It wasn't until the completion of
13 that investigation where it was
14 determined what the root cause
15 was.
16 And once the root cause was
17 determined, we took the
18 appropriate action.
19 MR. HONIK: Let's take a
20 look at Tab 13, please.
21 (Document marked for
22 identification as Exhibit
23 PL-Talton-9.)
24 MR. TRISCHLER: Can we take

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1 a restroom break when you're done
2 with this document?
3 MR. HONIK: Yeah. I may, in
4 fact, not ask any questions about
5 this. So if you have a minute or
6 two for a couple predicates, we'll
7 take a break, okay?
8 MR. TRISCHLER: Yeah, that's
9 fine. Whenever you're done with
10 it.
11 BY MR. HONIK:
12 Q. Mr. Talton, are you familiar
13 or have you been familiar either through
14 your considerable job experience or
15 preparation for today, with 21 C.F.R.
16 Section 211.1 which has to do with cGMP
17 standards for pharmaceuticals?
18 I'm not referring to the
19 document, sir.
20 A. Valsartan, my area of
21 responsibility. But I'm aware that
22 pharmaceutical products are required to
23 be manufactured in compliance with
24 current good manufacturing practice.

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1 Q. And do you know as a general
2 proposition that there is a specific Code
3 of Federal Regulation, namely at 21
4 Section 211 that speaks to that and deals
5 with that?
6 A. That sounds right. I don't
7 have that C.F.R. reference to memory,
8 but...
9 Q. And just as almost an aside,
10 are you aware that that C.F.R. dealing
11 with current good manufacturing process
12 standards applies to both human and
13 animal drugs?
14 A. It is my understanding it
15 applies generally to all pharmaceutical
16 products.
17 Q. Okay. But specifically it
18 applies, in the context, somewhat
19 ironically, to both animal and human
20 drugs, correct? I mean you said it when
21 you said all pharmaceutical products,
22 right?
23 A. Yes. Brand, generic, yes.
24 Products consumed for pharmaceutical use.

<p style="text-align: right;">Page 306</p> <p>1 Q. Consumed either by humans or 2 animals, correct?</p> <p>3 A. There are separate 4 regulations for animal drugs. We don't 5 really manufacture animal drugs.</p> <p>6 MR. HONIK: Okay. Why don't 7 we take our break now.</p> <p>8 THE VIDEOGRAPHER: Okay. 9 The time is 2:57 p.m. Off the 10 record.</p> <p>11 (Short break.)</p> <p>12 THE VIDEOGRAPHER: The time 13 is now 3:05 p.m. Back on the 14 record.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. So, Mr. Talton, when we 17 broke, we were looking -- starting to 18 look at exhibit -- this is 8, I believe.</p> <p>19 MR. HONIK: Are we up to 8?</p> <p>20 MR. DAVIS: This is 21 Exhibit 9.</p> <p>22 MR. HONIK: Thank you.</p> <p>23 BY MR. HONIK:</p> <p>24 Q. Which is the Guidance for</p>	<p style="text-align: right;">Page 308</p> <p>1 with that, if I may.</p> <p>2 If you go back to Page 7 --</p> <p>3 I'm sorry, I misspoke. If you go back to 4 Page 9, the preceding page, it says, 5 "Description of Manufacturing Process and 6 Process Controls."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And it actually gives in 10 parens, the section of the DMF, I think 11 it corresponds to the DMF section where 12 that would come in, namely S.2.2. Do you 13 see that?</p> <p>14 A. Yes.</p> <p>15 Q. And we've looked at -- we've 16 looked at numerous examples of sections 17 of the DMF corresponding to that section, 18 correct?</p> <p>19 A. We have referred to various 20 drug substance sections this morning.</p> <p>21 Q. And this section deals, in 22 fact, with descriptions of manufacturing 23 process and process controls, correct?</p> <p>24 A. Yes, that's the title of</p>
<p style="text-align: right;">Page 307</p> <p>1 Industry, Drug Substance, Chemistry, 2 Manufacturing, and Controls Information.</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And you see it's dated 6 August 6, 2010, this guidance?</p> <p>7 A. Yes.</p> <p>8 Q. And as the name implies, 9 it's a guidance dealing with 10 manufacturing and controls information 11 and the need to impart that to 12 regulators, correct?</p> <p>13 A. I would characterize that as 14 a summary of the information that should 15 be included to describe the drug 16 substance in a regulatory application.</p> <p>17 Q. That's an even better 18 description. And thank you for that.</p> <p>19 So if you look with me at 20 Page Number 10, there are specific 21 guidelines enumerated here.</p> <p>22 And again, this goes back to 23 2010. The section is Number 2. This is 24 part of Section B. Let me just frame it</p>	<p style="text-align: right;">Page 309</p> <p>1 this section.</p> <p>2 Q. So if we look then at 3 Page 10 at Subpart two, it gives a rather 4 detailed guidelines and guidance to what 5 goes into the description and how it 6 should be described. Specifically it 7 says, "Any process controls that are 8 considered critical process controls 9 should be highlighted."</p> <p>10 Do you see where it says 11 that?</p> <p>12 A. Yes.</p> <p>13 Q. And then the bullet points 14 that come after that are specific 15 examples or detailed description of the 16 manufacturing process and process 17 controls that should be included. Do you 18 see that?</p> <p>19 A. Yes.</p> <p>20 Q. And by the way, and I 21 apologize, I don't know that I asked you. 22 Did you say you've seen this guidance 23 before?</p> <p>24 A. I'm familiar with this</p>

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1 guidance.

2 Q. Okay. And as head of -- as

3 global head of regulatory affairs, I mean

4 this would be one of the source documents

5 that provide guidance to Mylan in

6 complying with its obligations, correct?

7 A. It's one of many that we

8 might refer to.

9 Q. To be sure, there are any

10 number of guidances that may impact and

11 be followed, but this is one of them to

12 be sure, correct?

13 A. Yes, this -- this

14 memorializes the FDA's expectations of

15 what would be included in the drug master

16 file for a drug substance.

17 Q. That's perfect.

18 So if we look at the bullet

19 points together to be sure they want and

20 guide that there is a detailed

21 description of each manufacturing step,

22 correct?

23 A. The document states that.

24 Q. Starting materials and

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1 intermediate used in each step need to be

2 specified, correct?

3 A. That's stated as well.

4 Q. Solvents, reagents, and

5 auxiliary materials used in each step

6 with chemical or biological names and

7 quantities specified should be included

8 as well, correct?

9 A. That's also listed here.

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 312

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 BY MR. HONIK:

16 Q. Okay. Maybe we'll some

17 other guidance that is clearer than this

18 one.

19 And then it goes on to

20 identify in quite detail the various

21 processes, for example, involving

22 combining intermediate or drug substance

23 batches, dilutants, and so forth. Do you

24 see that?

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1 A. Yes.

2 Q. If you turn with me to

3 Page 15. Any conceivable question about

4 whether recovery processes should be

5 included in a DMF or not is really

6 answered on this page.

7 Do you see the Subpart C,

8 Recovery?

9 A. Yes.

10 Q. And it says, and I quote,

11 "The use of recovered solvents and

12 recycling of filtrates to recover

13 reactants, intermediates, or drug

14 substance, including for the purpose of

15 producing or isolating additional

16 crystals, should be described in S.2.2,"

17 correct?

18 A. That's what's stated here.

19 Q. And, in fact, it says,

20 "Recovery operations should be adequately

21 controlled so impurity levels do not

22 increase over time."

23 Doesn't it say that?

24 A. It does state that.

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1 Q. And it's clear, sir, in
2 preparation for today that you can't
3 point to a single instance in which Mylan
4 revealed in its DMF to the FDA any aspect
5 of the recovered solvent process used in
6 valsartan API, correct?
7 MR. TRISCHLER: Objection.
8 Asked and answered.
9 THE WITNESS: It's not a
10 requirement. And what they are
11 putting here, and we did disclose
12 in the drug master file that
13 recovered solvents were being
14 used, we actually specified that.
15 So we did -- we did meet this
16 guidance.
17 BY MR. HONIK:
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 315

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 Q. And that would reflect a
5 detailed description of the recovered
6 solvent process that your own chemists
7 identified as part of how you'd produce
8 valsartan, correct?
9 A. I can tell you what the
10 interpretation of this and how it applies
11 to the U.S. drug master files.
12 It's asking that you -- if
13 you use recovered solvents, you need to
14 specify that, which we did in the drug
15 master file.
16 You have to include the
17 quality standard by which it must meet,
18 which we did.
19 So when you say described in
20 your application, it was described in our
21 DMF that we used recovered solvents.
22 Q. Mylan listed the fact that
23 recovered solvent was used, but it didn't
24 describe how it recovered it. You agree

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1 with that statement, don't you?
2 MR. TRISCHLER: Objection to
3 the form. Asked and answered.
4 THE WITNESS: We disclosed
5 that recovered solvents was used,
6 but we did not describe in detail
7 in the DMF of how they were
8 recovered.
9 BY MR. HONIK:
10 Q. Thank you.
11 A. Nor was it a requirement --
12 nor is it a requirement to do so.
13 Q. You see the guideline which
14 guides industry to describe the process,
15 correct?
16 A. Yes. And it's a guideline,
17 which does not mean -- it's not a
18 regulation. It's a guideline.
19 And I'm telling you based on
20 my experience and understanding, is
21 routinely during this time, you did not
22 have to include the details of a recovery
23 process in a drug master file.
24 Q. Can you tell me under what

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1 circumstances Mylan is permitted to
2 ignore a guideline?
3 A. I would argue no guideline
4 has been ignored. We did disclose that
5 recovered solvents were being used. It
6 was described in the drug master file.
7 Just not the details of the recovery
8 process, which is not an expectation.
9 Q. Do you see the next
10 paragraph, sir, that says, "Recovered
11 solvents can be used with or without
12 further processing to improve the quality
13 of the solvent as long as the quality of
14 the recovered solvent is appropriate for
15 its intended use."
16 The use of recovered
17 solvents, including the point at which
18 they might be used in the process, should
19 be included in the description of the
20 manufacturing process?"
21 Did I read that correctly?
22 A. You did. And that's exactly
23 what the DMF does. It describes the
24 solvent. It discloses that it's

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1 recovered. It discloses what quality
2 standard it's intended to meet. And it's
3 described in the manufacturing process
4 that's used. So I don't know where the
5 disconnect is.

6 Q. "Information should be
7 provided on whether (1) any processing is
8 done to improve the quality of the
9 recovered solvent with a brief
10 description of the process, for example,
11 distillation."
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 Q. Agreed.
19 It also -- the guidance also
20 says, "Appropriate specifications for
21 recovered solvents should be included in
22 S.2.3."
23 That wasn't done by Mylan,
24 was it?

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1 MR. TRISCHLER: Objection to
2 form.
3 THE WITNESS: No, it was
4 done.
5 In fact, we talked about
6 this earlier, whether a solvent is
7 recovered or virgin, it has to
8 meet the same quality standard and
9 we complied with that.
10 BY MR. HONIK:
11 Q. None of the specifications
12 for that were revealed however, correct?
13 MR. TRISCHLER: Objection to
14 form.
15 THE WITNESS: The
16 specifications for your solvents
17 would be included in the drug
18 master file.
19 BY MR. HONIK:
20 Q. Sir, what does the term
21 "appropriate specifications" mean to you
22 in that sentence?
23 A. The quality standard by
24 which that material must meet before you

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1 use it.
2 Q. And what in the DMF reveals
3 those specs?
4 A. The drug master file should
5 contain a specification or a list of
6 acceptance criteria that the solvent
7 should comply with before it's released
8 for use.
9 Q. Mr. Talton, because the DMF,
10 according to you while listing the use of
11 recovered solvent nonetheless doesn't
12 describe the actual process, it's true
13 that the FDA was unaware, as we've seen,
14 about the way in which the recovery
15 occurred until they had to ask Mylan in
16 2018; is that correct?
17 MR. TRISCHLER: Objection to
18 form.
19 THE WITNESS: Based on what
20 I've seen, the process by which
21 the solvent was recovered was not
22 specifically described.
23 But remember a drug master
24 file is submitted to the FDA for

Page 321

1 review. So there was a technical
2 review of the application done in
3 context with our abbreviated new
4 drug application, and FDA found it
5 acceptable.
6 BY MR. HONIK:
7 Q. Didn't you tell me earlier
8 that they don't accept it, that they only
9 point out deficiencies?
10 A. Nope, that's not what I
11 said. I said FDA doesn't approve a drug
12 master file. But they review it in
13 connection with an abbreviated new drug
14 application.
15 Q. Yeah. And my question is
16 simply this. And I take your points,
17 namely that use of recovered solvent was
18 identified, just like that, without any
19 further description of the manner in
20 which that process would occur, because
21 Mylan wasn't obligated to. That's your
22 essential point, right?
23 A. The essential point it was
24 not a regulatory requirement to describe

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1 that in detail in the drug master file at
2 that time.
3 Q. And, therefore, Mylan
4 didn't. And my question, therefore, is
5 the first time that Mylan revealed it to
6 the FDA was when Mylan was -- when FDA
7 was scratching its head to figure out how
8 NDEA could get in there. And for the
9 first time you revealed the recovery
10 process, in 2018, correct?
11 MR. TRISCHLER: Objection to
12 form.
13 THE WITNESS: No. We had --
14 we had disclosed that we had used
15 recovered solvents. It wasn't
16 until following completion of the
17 investigation where the root cause
18 was determined.
19 BY MR. HONIK:
20 Q. I'm asking a very simple
21 timeline question.
22 When the DMF was submitted
23 in 2013, you and I both agree that Mylan
24 said we may use recovered solvent or

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1 fresh solvent. Full stop. Isn't that
2 correct?
3 A. Both of those options were
4 disclosed in the drug master file.
5 Q. And apart from disclosing
6 that you may use either fresh or
7 recovered solvent, the process by which
8 recovery would occur, the ingredients
9 used to recover it were not disclosed in
10 the DMF because, according to you, Mylan
11 wasn't required to; isn't that right?
12 A. It wasn't required to be
13 described in detail. And as I said, the
14 drug master file was reviewed and
15 technically accepted by FDA as is.
16 Q. What's the difference
17 between "approved" or -- and "accepted"
18 as you're using those terms?
19 A. When a drug master file is
20 submitted to the FDA, they do a
21 completeness assessment to ensure that
22 the application is complete and has all
23 the required components.
24 Then they deem it available

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1 for reference. In other words, as an
2 ANDA applicant, you are now authorized to
3 refer to that DMF because it has
4 undergone a preliminary assessment and
5 determined to be complete.
6 As part of the official ANDA
7 review, the DMF now will get reviewed in
8 great detail to make sure that it's
9 suitable for use in your dosage form.
10 Q. But the fact remains that
11 there was nothing in the way of approval
12 by the FDA of the submitted DMF by Mylan,
13 there was no approval, correct?
14 A. FDA refers to the drug
15 master file in parallel with review of
16 the ANDA. So that -- the DMF and the
17 ANDA constitutes the review.
18 Q. But no approval is ever
19 forthcoming, that's what you told me
20 earlier, right?
21 A. No approval of a DMF, per
22 se, but approval of an ANDA.
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 BY MR. HONIK:
15 Q. I want to go back for a
16 minute if I may to Exhibit 7. I think
17 you have that there. That is the DMF
18 that we've been speaking of, or more
19 specifically, questions that were posed
20 through Mr. Plastina regarding the DMF.
21 Do you have that exhibit,
22 Mr. Talton?
23 A. Just a second.
24 Q. Sure.

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1 MR. TRISCHLER: Is Exhibit 7
2 the document you put up on the
3 screen, Ruben?
4 MR. HONIK: I think you are
5 right. So you don't have a
6 hardcopy, right?
7 MR. DAVIS: I can reshare.
8 MR. HONIK: No, let's --
9 let's -- Mr. Talton, I apologize,
10 I thought you had a copy. But
11 that's fine.
12 We can go back quickly to
13 one section of it, and that would
14 be Page 4 of 14 that comprised the
15 inquiry from the FDA.
16 BY MR. HONIK:
17 Q. And just to contextualize
18 the question for you, Mr. Talton. You'll
19 recall this was -- this was the letter
20 sent to Mr. Plastina on the DMF for
21 valsartan and the questions that Mylan
22 was asked to respond to. And you
23 indicated that it would have gone by
24 definition to Mr. Basade and his group.

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1 Do you remember talking
2 about that?
3 A. Yes.
4 Q. And Mr. Trischler took out
5 some pains to point out my error in
6 referring to it as having occurred in
7 July, when in fact it occurred in
8 November of 2018. Do you remember that?
9 A. Yeah.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
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9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 BY MR. HONIK:

21 Q. Let's turn to previously

22 marked Owens Exhibit 9.

23 (Previously marked

24 Exhibit PL-Owens-7, PL-Owens-9,

Page 332

1 PL-Owens-10.)

2 BY MR. HONIK:

3 Q. Do you have that in front of

4 you, Mr. Talton?

5 A. Just a second.

6 Q. I'm going to place 9 and 10

7 in front of you --

8 THE WITNESS: Do I have

9 Owens-9?

10 MR. TRISCHLER: I don't

11 think you have them yet.

12 MR. HONIK: While you are

13 fetching them, maybe get 9, 10 and

14 7 please. Owens.

15 THE WITNESS: Okay. I have

16 7.

17 BY MR. HONIK:

18 Q. Okay. I'm going to start

19 with 9. Let me know when you have that.

20 A. I have 9.

21 Q. Okay. Do you have 10 as

22 well?

23 A. I do now, yes.

24 Q. You see that previously

Page 333

1 marked Plaintiffs Owens Exhibit 9 is an

2 e-mail from a Baburao Konudula to

3 Mr. Abbineni.

4 Do you see that?

5 A. Yeah.

6 Q. And the subject is

7 justification report for NDMA. And it

8 refers to an attachment called

9 Justification Report For NDMA Impurity in

10 Sartans.

11 Do you see that?

12 A. Yes.

13 Q. And in the body of this

14 transmittal, the e-mail being July 23,

15 2018, you see that the transmitter of the

16 attachment, namely the report, indicates

17 it's a draft.

18 Do you see that?

19 A. Yeah.

20 Q. So if we have a draft report

21 concerning NDMA impurity in sartan, did

22 you review either this e-mail or

23 Plaintiffs -- excuse me, Owens

24 Exhibit 10, which is the attachment,

Page 334

1 before today?

2 A. No, I don't recall seeing

3 this document.

4 Q. If you look with me at

5 Owens-10 which is the very attachment

6 that the e-mail refers, it's entitled

7 Evaluation of Products Manufactured in

8 Mylan Regarding NDMA.

9 Do you see that, sir?

10 A. Yes.

11 Q. And if you turn to the first

12 page after that, in the report at the top

13 you'll see Table 1?

14 A. I see it.

15 Q. And in the draft report,

16 immediately following the table which

17 lists the sartan drug, and the chart

18 which reveals use of sodium nitrite

19 quenching in the presence of the product,

20 et cetera, do you see the asterisk at the

21 bottom of the table?

22 A. Yes.

23 [REDACTED]

24 [REDACTED]

Page 335

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 Q. Do you know who authored

5 this?

6 A. No, I do not.

7 Q. In Owens-9 it says, "Draft

8 report was prepared and sent to Naveen

9 for review."

10 Do you know who Naveen is?

11 A. No, I do not.

12 Q. And in the e-mail thread

13 immediately before that, Anjireddy Unit 2

14 is writing to Anjireddy Emani, do you

15 know either of those individuals?

16 A. No, I do not.

17 Q. Okay. But nonetheless, you

18 see where in both parts of the e-mail

19 thread it refers to this report as a

20 draft, right?

21 A. Yeah.

22 Q. Do you have any way of

23 knowing whether this report goes to

24 regulatory affairs, someone in your

Page 336

1 office?

2 A. I'm not aware of having this

3 come to regulatory before.

4 Q. Given the date of July 2018,

5 you were aware at regulatory affairs, as

6 Mylan was, of the recalls that were

7 starting and the problems associated with

8 the presence of nitrosamines in ARBs,

9 correct?

10 A. I think it was around July

11 when the issue first surfaced, yes.

12 Q. And suffice to say, you in

13 your office in regulatory affairs began

14 to, A, be aware, and B, observe activity

15 at Mylan to try to identify whether

16 nitrosamines were a problem and what

17 their source might be in your valsartan,

18 correct?

19 A. We became of the inquiry,

20 but it wasn't until the investigation was

21 more advanced or we began to get

22 inquiries from health authorities that

23 regulatory affairs was more involved or

24 more aware.

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1 Q. Well, I get that statement.

2 And we can unpack that a little bit as we

3 go along.

4 But suffice to say, it was

5 not a secret, even as early as July 2018

6 that there were recalls occurring with

7 your competitors, Mylan's competitors in

8 this segment of the market, namely ARBs,

9 and sartans to be in particular,

10 revealing the presence of nitrosamines,

11 correct?

12 A. Regard -- concerning the

13 presence of NDMA specifically. That was

14 the initial inquiry.

15 Q. Absolutely. And this is

16 evidence that there was some evaluation

17 of Mylan's own products, vis-à-vis the

18 presence of NDMA in its products,

19 correct?

20 A. Of course, that was the

21 right thing to do. The issue arose and

22 we began an investigation with the

23 appropriate steps to take.

24 Q. I agree, paying attention in

Page 338

1 July was the right thing to do.
2 [REDACTED]

[REDACTED]

Page 340

1 [REDACTED]

[REDACTED]

Page 339

1 [REDACTED]

[REDACTED]

Page 341

1 [REDACTED]

[REDACTED]

Page 342

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19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 BY MR. HONIK:
4 Q. Okay. So that was the draft
5 report in July 2018 that was exchanged
6 internally at Mylan. And if you look
7 with me at previously marked Owens
8 Exhibit 7, you'll see that the native
9 format information confirms that this is
10 a document named Valsartan Nitroso
11 Impurity Comment Response, and it's dated
12 13 August 2018.
13 Do you see that?
14 A. Yes.
15 Q. And you see that when you
16 turn to the first page, it's on Mylan
17 letterhead, with the Chestnut Ridge Road,
18 Morgantown, West Virginia, address. Do
19 you see that?
20 A. Yes.
21 Q. And it's referred to as a
22 cover letter for a response to
23 information request letter. Do you see
24 that?

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1 A. Yeah.
2 Q. That confirms, does it not,
3 that this is Mylan specifically
4 responding to a request for information
5 from the FDA, correct?
6 A. That's what it appears to
7 be.
8 Q. And it's sent to the FDA at
9 their Beltsville, Maryland, address and
10 it's officially signed by Michael
11 Plastina, who you've established through
12 your testimony is the agent on behalf of
13 MLL for valsartan DMF, right?
14 A. That's correct.
15 Q. Now, have you seen this
16 response before today?
17 A. Yes.
18 Q. And did you look at it in
19 preparation for today's testimony?
20 A. I mean I perused it. I
21 didn't read every -- every question,
22 every response.
23 Q. No, I get that. And I
24 apologize.

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1 All I want to make clear is,
2 did you see it in the ordinary course of
3 your work or employment or specific to
4 your preparation for today or both?
5 A. Specific to the preparation
6 for today. As I mentioned previously,
7 drug master file communications are
8 directly from MLL to FDA through the
9 agent and not something I would review in
10 the normal course of business.
11 Q. So you saw this document and
12 the responses on behalf of Mylan for the
13 first time in connection with today?
14 A. In preparation for the
15 deposition.
16 Q. Yeah. How much before today
17 did you first see this document?
18 A. The preparation took place
19 over the last two weeks, so within the
20 last couple of weeks.
21 Q. Can you turn to the part of
22 the response that begins with a front
23 page called Annexure-2? You have to flip
24 about two-thirds or so the way through

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1 the document. You'll come to something
2 that says, "Annexure-2."
3 Do you have that?
4 A. Not yet. Just a second.
5 Q. Sure.
6 A. Okay.
7 Q. Do you remember reading the
8 Annexure-2 in this response from Mylan to
9 the FDA?
10 A. Not in great detail, no.
11 Q. Do you see, if you turn to
12 the next page which is called Page 1 of
13 5. At the top it says, "Mylan's response
14 to impurity NDMA in valsartan drug
15 substance."
16 Do you see that?
17 A. Yes.
18 Q. And it says, and I quote,
19 "Mylan agrees that NDMA can be formed
20 during the formation of the tetrazole
21 ring by reaction of dimethylamine which
22 may be present as an impurity or
23 degradant in the solvent,
24 dimethylformamide, DMF, and sodium

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1 nitrite under acidic conditions where
2 nitrous acid is formed."
3 Do you see that?
4 A. Yes.
5 Q. So that's an acknowledgement
6 of what essentially turned out to be the
7 root cause investigation revealing the
8 manner in which nitrosamine got into the
9 valsartan, correct?
10 MR. TRISCHLER: Objection to
11 form.
12 THE WITNESS: At this point
13 in time it was probably ongoing
14 investigation by both Mylan as
15 well as the health authority.
16 BY MR. HONIK:
17 Q. All right. I agree with
18 that. But all I'm really asking you,
19 sir, is what we just -- what I just read
20 to you and you heard and acknowledged my
21 reading, that's the actual description of
22 what ended up being the cause of the
23 nitrosamine, right?
24 A. No. This paragraph you just

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1 read is specific to NDMA. So Mylan was
2 rationalizing how that potentially could
3 be formed based on the chemistry.
4 Q. Right. And this is -- this
5 is a description of the chemistry that
6 could lead to the formation of NDMA,
7 correct?
8 A. That appears to be what is
9 described here.
10 Q. And it says that you need
11 sodium nitrite under acidic conditions
12 thereby forming nitric acid. And then
13 there's a further reaction with, in this
14 case dimethylamine, which produces NDMA.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 BY MR. HONIK:
20 Q. Correct. And this, this
21 sentence, long sentence that we just
22 read, so I can move on, is just a
23 descriptor of the chemical reactions
24 which in this case produces NDMA. And

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1 I'm just establishing that ultimately the
2 root cause analysis by Mylan revealed
3 similarly that that reaction in the
4 presence of triethylamine produces NDEA,
5 correct?
6 MR. TRISCHLER: Objection to
7 form and scope.
8 THE WITNESS: As part of the
9 overall investigation which was
10 active and ongoing at this time.
11 BY MR. HONIK:
12 Q. That's true.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 BY MR. HONIK:
23 Q. Thank you.
24 As we saw in the draft

Page 351

1 response, the drafter of the response was
2 quite clear in pointing out that sodium
3 nitrite is, in fact, used in the recovery
4 process.
5 Do you remember that
6 asterisk?
7 A. Yes, I remember the --
8 MR. TRISCHLER: Objection to
9 form.
10 THE WITNESS: Yes, I
11 remember seeing the asterisk.
12 BY MR. HONIK:
13 Q. If you look down to the
14 middle of this page, 1 of 5, in the
15 official response Mylan proffered to the
16 FDA, underneath the chemical diagramming
17 it says, and I quote, "Mylan does not use
18 dimethylamine or its source nitrous acid
19 or its source as reagents/solvents in the
20 manufacture of intermediate of valsartan
21 CMVEH."
22 Do you see that?
23 A. Yes.
24 Q. "Or further stages of

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1 valsartan manufacturing process. Hence
2 the formation of NDMA in valsartan
3 manufactured by Mylan is ruled out."
4 Did I read that correctly?
5 A. That's what it states in the
6 document.
7 Q. That's not a true statement,
8 is it?
9 A. At the time this document
10 was written, yes, it was a true
11 statement.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
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<p>Page 358</p> <p>1 [REDACTED]</p>	<p>Page 360</p> <p>1 [REDACTED]</p>
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Page 362

1 [REDACTED]
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4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 BY MR. HONIK:
8 Q. Sir, your -- if I'm taking
9 your testimony correctly, what you're
10 really saying is that Mylan claims that
11 the nitrosamine problem was not
12 foreseeable, right?
13 MR. TRISCHLER: Objection to
14 form. Objection. Beyond the
15 scope.
16 THE WITNESS: I can't
17 comment as to whether it was
18 foreseeable or not. I know there
19 was an extensive investigation.
20 We were as responsive as we could
21 be, and worked very diligently to
22 get to the root cause so that we
23 could take the appropriate
24 corrective actions.

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1 BY MR. HONIK:
2 Q. Sir, respectfully we just
3 read a formal response as late as August
4 of 2018 from Mylan saying that there's no
5 way NDMA could occur from your process.
6 Didn't we see that together?
7 A. That's what as the date of
8 this document is true, based on the
9 information we had available to us at the
10 time.
11 Q. And you said to me, not even
12 implicitly, you've said to me expressly
13 that it was not foreseeable by Mylan that
14 a nitrosamine problem could affect your
15 valsartan, isn't that what you've said to
16 me all day under oath?
17 MR. TRISCHLER: Objection to
18 the form. Objection. It's beyond
19 the scope.
20 THE WITNESS: I don't think
21 we talked about foreseeable. Or
22 we've been looking at documents,
23 and I've been trying to answer
24 those as responsively as I can.

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1 BY MR. HONIK:
2 Q. Fair enough. So I'll ask
3 you this question then, as head of
4 regulatory affairs.
5 Was it foreseeable at any
6 point based on anything you've seen thus
7 far today or in your preparation for
8 today for Mylan to know that nitrosamines
9 were capable of being produced?
10 MR. TRISCHLER: Objection to
11 the form. Objection. No
12 foundation with this witness.
13 Objection that it's beyond the
14 scope.
15 THE WITNESS: That would be
16 up to our scientific development
17 staff to determine that. There's
18 no way I can predict what was
19 foreseeable.
20 BY MR. HONIK:
21 Q. If it was foreseeable as
22 regulatory affairs head, would you have
23 had to reveal it to the FDA?
24 MR. TRISCHLER: Objection to

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1 form.
2 THE WITNESS: That's another
3 hypothetical and we've gone over
4 this a number of times as well, in
5 that we rely upon the science,
6 scientists to provide us with
7 complete information that we can
8 put in our registration, and I
9 rely on that as being truthful and
10 accurate.
11 BY MR. HONIK:
12 Q. But we saw together how
13 Mylan claimed compliance with the
14 European guideline that says you are
15 obliged to call out carcinogens and
16 genotoxic impurities. Do you remember
17 seeing that?
18 MR. TRISCHLER: Objection to
19 the form. Misstates and
20 mischaracterizes the document.
21 But you can answer the
22 question if you can, not --
23 notwithstanding the fact it's
24 already been asked and answered

<p>Page 366</p> <p>1 multiple times.</p> <p>2 THE WITNESS: We did look at</p> <p>3 a European guidance document on</p> <p>4 genotoxic impurities this morning</p> <p>5 if that's what you're referring</p> <p>6 to.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. That's right.</p> <p>9 And in it we saw how, if</p> <p>10 there was even a potential to generate a</p> <p>11 genotoxic impurity, it has to be</p> <p>12 identified to the regulator, isn't that</p> <p>13 what we saw together?</p> <p>14 MR. TRISCHLER: Object to</p> <p>15 the form. Beyond the scope.</p> <p>16 THE WITNESS: And Mylan</p> <p>17 claimed certification to that,</p> <p>18 compliance with that guidance</p> <p>19 based on the information we had</p> <p>20 available.</p> <p>21 So, again, it was a true and</p> <p>22 accurate statement at the time it</p> <p>23 was written.</p> <p>24 BY MR. HONIK:</p>	<p>Page 368</p> <p>1 departments. I cannot answer that</p> <p>2 question.</p> <p>3 Q. Sure.</p> <p>4 A. You need to talk about --</p> <p>5 you need to speak to the people who were</p> <p>6 responsible for developing the API and</p> <p>7 what process they used to determine the</p> <p>8 impurity profile.</p> <p>9 Q. I'm asking you in the</p> <p>10 context of the person communicating with</p> <p>11 your regulator. And the question in that</p> <p>12 frame, sir, is, are you not obliged if</p> <p>13 you can foresee a genetic -- a genotoxic</p> <p>14 impurity to reveal that potential to your</p> <p>15 regulator, yes or no?</p> <p>16 MR. TRISCHLER: Objection.</p> <p>17 Asked and answered.</p> <p>18 THE WITNESS: That's part of</p> <p>19 the development process. And so</p> <p>20 if the conclusion is there's no</p> <p>21 formation, then we rely upon that</p> <p>22 and we communicate that to the</p> <p>23 regulator.</p> <p>24 BY MR. HONIK:</p>
<p>Page 367</p> <p>1 Q. But here is the question</p> <p>2 that I'm trying to ask you.</p> <p>3 Does not the guidance</p> <p>4 require in this case Mylan, like any</p> <p>5 other pharmaceutical company attempting</p> <p>6 to comply with that guidance, to foresee</p> <p>7 a genetic impurity, isn't there a</p> <p>8 requirement of foreseeability?</p> <p>9 MR. TRISCHLER: Objection to</p> <p>10 the form.</p> <p>11 THE WITNESS: We made the</p> <p>12 certification, so obviously we</p> <p>13 didn't have a foreseeable</p> <p>14 knowledge or we would have made</p> <p>15 the claim.</p> <p>16 BY MR. HONIK:</p> <p>17 Q. Exactly. You would have</p> <p>18 revealed it if it were foreseeable,</p> <p>19 that's my question; isn't that right?</p> <p>20 A. You're asking the wrong</p> <p>21 person this question. You're asking</p> <p>22 about development process, prediction of</p> <p>23 impurities. I'm a recipient of</p> <p>24 conclusions coming from those</p>	<p>Page 369</p> <p>1 Q. Sir, is your answer yes, it</p> <p>2 is an obligation of us if our scientists</p> <p>3 tell us, is that your answer?</p> <p>4 A. My answer is I can't answer</p> <p>5 your question because the question that</p> <p>6 you're asking is a development type</p> <p>7 question. The person responsible for the</p> <p>8 development of APIs would be better</p> <p>9 suited to answer that question. I don't</p> <p>10 know the details of what process they go</p> <p>11 through to determine what potential</p> <p>12 impurities might be present.</p> <p>13 Q. If -- if Mylan's development</p> <p>14 process professionals, the chemists who</p> <p>15 develop the process could look at the</p> <p>16 chemistry and foresee the potential for a</p> <p>17 genotoxic impurity from the use of</p> <p>18 certain chemicals at the same time, is</p> <p>19 not there an obligation on the one hand</p> <p>20 to reveal it to you and on the other hand</p> <p>21 for you to reveal it to the FDA?</p> <p>22 MR. TRISCHLER: Objection,</p> <p>23 asked and answered.</p> <p>24 THE WITNESS: Again, you're</p>

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1 asking a development question,
2 what is the process by which APIs
3 were developed and how they go
4 about establishing impurity
5 profiles.
6 I can't comment on that. I
7 don't know that process. I'm not
8 familiar with it.
9 BY MR. HONIK:
10 Q. Sir, I'm asking a
11 communication question about you as the
12 regulator -- regulation affairs person
13 and whether, if you had information from
14 your development people that it was
15 foreseeable that there could be a
16 genotoxic impurity, that you as the
17 regulatory head would have been obliged
18 to reveal that in turn to the FDA, that's
19 my question?
20 MR. TRISCHLER: Same
21 objection.
22 THE WITNESS: We rely upon
23 the scientists to provide us with
24 a comprehensive summary and a drug

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1 master file, controls, et cetera,
2 we rely upon that in regulatory.
3 So I rely on the scientists
4 to provide me with the right
5 information, then I share that
6 with the agency.
7 BY MR. HONIK:
8 Q. And if the scientists had
9 conveyed to you that it was foreseeable
10 that you could have the creation of
11 nitrosamines through the recovery
12 process, would you then have been obliged
13 to share that with the FDA?
14 A. Again, you're asking a
15 hypothetical. You know, they are
16 responsible for putting together the drug
17 master file, determining what the
18 impurity profile is. I rely upon their
19 conclusions, and that's what I
20 communicate to the health authorities.
21 Q. Agreed.
22 A. And if there's a question
23 about that, then that goes back to the
24 scientists to address, as you can see by

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1 the evidence of the communications back
2 and forth to the health authorities.
3 Q. If -- if you had been told
4 that there was a foreseeable possibility
5 that nitrosamines could be formed under
6 the European guidance that Mylan claimed
7 compliance with, would not Mylan have
8 been obliged to reveal that fact and
9 indeed to pursue an alternative if it was
10 available?
11 MR. TRISCHLER: Objection.
12 Asked and answered.
13 THE WITNESS: You are asking
14 a hypothetical. I'm not aware of
15 any foreseeable activity around
16 that.
17 Again, I rely upon what we
18 receive from the scientists.
19 You're asking -- you're asking
20 this question to the wrong person.
21 I don't know how to say that any
22 further.
23 You're asking a fundamental
24 API development question, not a

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1 regulatory question.
2 BY MR. HONIK:
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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1 [REDACTED]

2 [REDACTED]

3 BY MR. HONIK:

4 Q. You're not responding to my

5 question, but we're going to take a

6 five-minute break.

7 A. I disagree, but...

8 THE VIDEOGRAPHER: The time

9 is 4:09 p.m. We're off the

10 record.

11 (Short break.)

12 THE VIDEOGRAPHER: The time

13 is now 4:19 p.m. Back on the

14 record.

15 BY MR. HONIK:

16 Q. Now, Mr. Talton, before we

17 took a break, we were talking about

18 whether or not it was foreseeable that

19 nitrosamines could be a problem based on

20 the development and process development

21 information that was known to Mylan.

22 Do you remember we were

23 talking about that?

24 A. Yes.

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1 Q. I recognize that we kind of

2 went round and round about it, and I

3 certainly don't mean to annoy you. But

4 this is an important area and I do want

5 to pursue it a little further with some

6 additional documents.

7 So I just want to frame for

8 you some additional information that I'm

9 going to place in front of you on this

10 point of what was knowable or foreseeable

11 in terms of the problem that was so

12 clearly identified in 2018.

13 Are you with me so far?

14 MR. TRISCHLER: Objection.

15 Objection to the form. I don't

16 think there's a question pending.

17 MR. HONIK: There is not.

18 I'm just asking if he understands

19 this little predicate or

20 background that I'm offering which

21 I'm hoping will make the next

22 series of questions a little bit

23 more digestible.

24 BY MR. HONIK:

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1 Q. Do you understand me so far?

2 A. Yes. I'm fine. But if it's

3 related to the development process,

4 you're -- I'm not the right person to be

5 asking those questions. But you can

6 certainly ask what you wish.

7 Q. Thank you.

8 So I want to call up a

9 previously marked exhibit Snider-18,

10 which for the record is a warning letter

11 that was issued, 29, November, 2019, from

12 the FDA to Mylan with certain

13 observations that were called out.

14 (Previously marked

15 PL-Snider-18.)

16 BY MR. HONIK:

17 Q. Sir, this is a confidential

18 Mylan document produced to us. Appears

19 to be 17 pages, and as I mentioned it is

20 a warning letter or the contents of a

21 warning letter from the FDA.

22 Is this something you've

23 seen before today?

24 A. Yes, I'm aware of the

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1 receipt of this warning letter.
2 Q. Okay. And did you become
3 aware of it in realtime back in 2019 or
4 did you see it for the first time in
5 preparation for today or both?
6 A. Both.
7 Q. Are you aware of Mylan
8 having engaged an outside consultant by
9 the name of Lachman?
10 A. Yes, I'm aware that we've
11 used them periodically on supporters for
12 a variety of matters.
13 Q. And how far back has Mylan
14 been relying upon or using Lachman as a
15 consultant?
16 A. That I can't answer. I can
17 tell you from a regulatory perspective
18 we've used them on occasion throughout my
19 20 years at Mylan, but I can't comment as
20 to how much quality may have used them.
21 Q. Understood. And just based
22 on your knowledge, how far back would you
23 say there's been a professional
24 relationship between Mylan and Lachman,

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1 that is how long have you been using
2 them, how far back?
3 A. As I stated, I'm aware that
4 we've used them at least on and off the
5 last 20 years of my tenure at Mylan.
6 Q. Okay.
7 A. But again, I can't comment
8 about quality's utilization of them.
9 Q. Beyond acknowledging that
10 not only did you rely on them in
11 regulatory, but development may have used
12 them as well, correct?
13 MR. TRISCHLER: Objection to
14 form, foundation.
15 THE WITNESS: I wouldn't
16 know whether or not they consulted
17 with them or not.
18 BY MR. HONIK:
19 Q. Okay. But suffice to say,
20 you have known about them and used them
21 as consultants, correct?
22 A. Yes. We've used them on
23 occasion for regulatory consulting and
24 I'm aware that quality uses them on

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1 occasion to help with inspections.
2 Q. Okay. And when you say
3 "quality uses them," do you know in what
4 context or for what purpose they use
5 them?
6 A. No, that would be a quality
7 engagement and I'm not familiar with
8 those engagements.
9 Q. And tell me in a little more
10 detail how you from time to time would
11 come to rely on Lachman, you in
12 regulatory.
13 A. Maybe for a specific
14 regulatory sort of strategy question or,
15 you know, maybe something that we needed
16 their assistance in filing a citizens
17 petition to help petition the FDA for a
18 certain action. Things like that.
19 Q. Okay. And you are aware
20 that the scope of their consultancy
21 expertise extends to both quality issues
22 as well as regulatory issues?
23 A. Yes, I'm aware that they at
24 least offer those two types of services.

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1 Q. Okay. And when you've had
2 occasion to use them, have you had direct
3 or personal contact with them yourself?
4 A. I have interacted with Bob
5 Pollock, who is the Lachman
6 representative directly on a couple of
7 occasions, but it's been a long time
8 since I've interacted directly with him.
9 Q. And would you mind spelling
10 Bob's last name for me? I didn't quite
11 catch it.
12 A. Pollock, P-O-L-L-O-C-K.
13 Q. Thank you. I appreciate it.
14 Turning your attention to
15 Exhibit Snider 18 previously marked, on
16 Page 1 you see the observation from the
17 FDA which says, "Failure to have adequate
18 written procedures for the receipt,
19 identification, testing and handling of
20 raw materials."
21 Do you see that?
22 A. Yes.
23 Q. And you see how in that
24 first paragraph there in that long first

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1 sentence it talks about contamination and
 2 cross-contamination with nitrosamine
 3 impurities such as NDMA and NDEA.
 4 Do you see that?
 5 A. Yes.
 6 Q. And then the sentence that I
 7 want to focus in on is the one that says,
 8 "Your firm," meaning Mylan, "had not
 9 anticipated the presence of NDMA or NDEA
 10 impurities based on your assessment of
 11 the API manufacturing process."
 12 Do you see that?
 13 A. Yes, I see that sentence.
 14 Q. And I take it to mean
 15 that -- that the FDA was expecting you to
 16 anticipate that presence if it was
 17 anticipatable.
 18 Do you read that the same
 19 way?
 20 MR. TRISCHLER: Objection to
 21 form.
 22 THE WITNESS: That's a --
 23 that's an observation from a field
 24 inspector and that would be their

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1 opinion of what they observed
 2 during the inspection.
 3 BY MR. HONIK:
 4 Q. To be sure.
 5 But the sentence I think
 6 fairly suggests that at least the FDA was
 7 wondering if it wasn't, in fact,
 8 foreseeable by your company, Mylan, to
 9 anticipate the presence of those
 10 impurities, again, based on assessing the
 11 manufacturing process. Is that a fair
 12 read of that sentence and opinion?
 13 MR. TRISCHLER: Objection --
 14 excuse me.
 15 Objection to the form.
 16 THE WITNESS: That was the
 17 opinion of that investigator that
 18 we had not anticipated the
 19 presence.
 20 BY MR. HONIK:
 21 Q. And it suggests to me, and
 22 you tell me if you agree, that at least
 23 in the opinion of that investigator, it
 24 should have been foreseeable?

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1 MR. TRISCHLER: Objection to
 2 form.
 3 THE WITNESS: I can't make
 4 that conclusion from that
 5 statement.
 6 BY MR. HONIK:
 7 Q. Okay. Fair enough.
 8 If you turn the page with me
 9 to the very next page, we've got Mylan's
 10 response, right?
 11 A. Yeah.
 12 Q. And the response, as I read
 13 it now really is what you've been telling
 14 me for the last 20 minutes or more, and
 15 that is, "At the time Mylan's
 16 applications for valsartan products were
 17 approved, the potential for the formation
 18 of nitrosamine impurities was not known."
 19 That's what you've been
 20 telling me for the last hour or so,
 21 right?
 22 A. Yes, essentially.
 23 Q. And in fact, the point is
 24 punctuated by the next sentence that

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1 says, "Until NDMA was first detected in
 2 valsartan produced by another API
 3 manufacturer in 2018, the entire
 4 pharmaceutical industry and regulators
 5 had not anticipated the potential for
 6 formation of nitrosamines in ARBs."
 7 Do you see that?
 8 A. That's what's stated here,
 9 yes.
 10 Q. And so Mylan's response here
 11 doubles down on the "it didn't know," by
 12 saying, "and nobody else knew," right?
 13 MR. TRISCHLER: Objection to
 14 form.
 15 THE WITNESS: I can only
 16 take the document for what's
 17 written here, and, you know, we
 18 read the sentence.
 19 BY MR. HONIK:
 20 Q. I know. But the meaning I
 21 draw from this, and you tell me if I'm
 22 incorrect, which is, as I stated, Mylan
 23 couldn't foresee and didn't know, nor did
 24 anybody else in the industry and

<p style="text-align: right;">Page 386</p> <p>1 regulators until 2018. Isn't that what 2 it conveys? 3 MR. TRISCHLER: Objection to 4 the form. 5 THE WITNESS: It's -- I mean 6 we can read the sentence. What it 7 states is until NDMA was first 8 detected produced by another 9 manufacturer, the industry and 10 regulators had not anticipated the 11 potential for formation. 12 BY MR. HONIK: 13 Q. In ARB -- 14 A. And I have to take that for 15 what it's worth. I didn't write this 16 document, I'm not qualified to interpret 17 it. 18 Q. Right. But you agree with 19 me that this is a communication with the 20 FDA, right? 21 A. It's a communication with 22 the FDA's office of compliance. This 23 communication would be managed through 24 our quality department, not regulatory</p>	<p style="text-align: right;">Page 388</p> <p>1 the FDA that it did not know, it could 2 not foresee the NDMA problem, nor did 3 anyone in the industry or among 4 regulators until 2018 with respect to the 5 risk of nitrosamines appearing in ARBs or 6 sartans. Isn't that what this conveys? 7 MR. TRISCHLER: Objection to 8 form. Objection. Asked and 9 answered. 10 THE WITNESS: We've read 11 those two sentences so... 12 We can read the sentences 13 again -- 14 BY MR. HONIK: 15 Q. I don't want to do that. I 16 want you to tell me if you agree with the 17 meaning I take from it. 18 MR. TRISCHLER: Object to 19 the form. 20 THE WITNESS: It's not 21 appropriate for me to interpret 22 this. I mean I think we need to 23 read the document for what it 24 states.</p>
<p style="text-align: right;">Page 387</p> <p>1 affairs. 2 Q. Regardless, you're here to 3 talk about communications between Mylan 4 and the FDA, correct? 5 A. That is correct. I just 6 wanted you to understand the context of 7 this is a quality document -- 8 Q. I do. 9 A. -- and a quality response. 10 Not a regulatory affairs one. 11 Q. I understand that. But you 12 were the one put up for this topic. And 13 I understand from you that you did some 14 preparation to understand some of the 15 quality related issues that impact this 16 area of questioning. Did you not? 17 A. Yes, I'm not saying we can't 18 talk about the document. I was trying to 19 help you understand that this is a 20 quality production, not a regulatory 21 affairs one. 22 Q. Regardless of what area of 23 the company it came from, this is a 24 communication from Mylan that conveys to</p>	<p style="text-align: right;">Page 389</p> <p>1 BY MR. HONIK: 2 Q. Sir, it is appropriate for 3 me to ask you your interpretation of it 4 because this is a communication from your 5 company Mylan to the FDA on an important 6 observation in connection with a warning 7 letter. 8 You're here today as a 9 designated representative for Mylan about 10 those communications. 11 So yes, I am asking you if 12 the mean -- the plain meaning to me of 13 these sentences, which is that Mylan 14 didn't know, Mylan couldn't foresee, nor 15 did anyone in the industry, have any idea 16 about the potential for nitrosamines in 17 ARBs, sartans, as of 2018. Isn't that 18 the -- isn't that what this says? 19 MR. TRISCHLER: Objection to 20 form. 21 THE WITNESS: It's similar 22 to that, but you're using 23 different words than what's stated 24 here. So I think for the record</p>

<p>Page 390</p> <p>1 we need to state what's here.</p> <p>2 And they are talking about</p> <p>3 the potential for formation, and</p> <p>4 that we had not anticipated the</p> <p>5 potential for formation.</p> <p>6 BY MR. HONIK:</p> <p>7 Q. Well, that's a good point.</p> <p>8 A. You're adding more words</p> <p>9 than that.</p> <p>10 Q. That's a fair point. So</p> <p>11 this goes even further and says the</p> <p>12 potential wasn't knowable, right?</p> <p>13 A. The word "potential" appears</p> <p>14 in this sentence, yes.</p> <p>15 Q. And Mylan is denying that</p> <p>16 there was even a potential for knowing</p> <p>17 that nitrosamines could be a problem with</p> <p>18 sartans, right?</p> <p>19 MR. TRISCHLER: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: It states that</p> <p>22 the potential for the formation of</p> <p>23 nitrosamine impurities was not</p> <p>24 known. That's what it states.</p> <p>Page 391</p> <p>1 BY MR. HONIK:</p> <p>2 Q. It was not known and not</p> <p>3 knowable by Mylan, right?</p> <p>4 A. The document states that the</p> <p>5 potential for formation was not known.</p> <p>6 Q. And so says Mylan, right?</p> <p>7 A. That's our statement.</p> <p>8 Q. Right. So take a look with</p> <p>9 me now at Gomas-10.</p> <p>10 Previously marked</p> <p>11 PL-Gomas-2.)</p> <p>12 MR. DAVIS: Gomas-2, Ruben?</p> <p>13 MR. HONIK: I misspoke.</p> <p>14 Gomas-2.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. We saw together how in</p> <p>17 Snider-18 the warning letter response,</p> <p>18 that was issued 29 November, 2019, right?</p> <p>19 A. Yes.</p> <p>20 Q. And before that date, did</p> <p>21 you know that Mylan through its quality</p> <p>22 people had in fact consulted your experts</p> <p>23 and consultants at Lachman?</p> <p>24 A. No, I was not aware of that.</p>	<p>Page 392</p> <p>1 Q. Okay. You didn't become</p> <p>2 aware of that consultation that Mylan had</p> <p>3 with Lachman in answering the FDA warning</p> <p>4 letter prior to today? In other words,</p> <p>5 you didn't look at any of this stuff in</p> <p>6 your preparation?</p> <p>7 A. I recall seeing the warning</p> <p>8 letter. I don't recall seeing this</p> <p>9 specific e-mail. Again, the warning</p> <p>10 letter is a document observation issued</p> <p>11 to quality.</p> <p>12 Quality is responsible for</p> <p>13 preparing the responses to those</p> <p>14 comments. Quality was responsible for</p> <p>15 engaging any external consultants they</p> <p>16 felt necessary. So I wouldn't have</p> <p>17 personal knowledge or business knowledge</p> <p>18 of those interactions.</p> <p>19 Q. You agree that Mylan has a</p> <p>20 duty of honesty in preparing responses to</p> <p>21 warning letters from the FDA, right?</p> <p>22 A. Yes. We will provide</p> <p>23 truthful and accurate information.</p> <p>24 Q. And if you -- if Mylan had</p> <p>Page 393</p> <p>1 acquired information from any source in</p> <p>2 this instance that revealed that it was</p> <p>3 foreseeable and knowable that nitrosamine</p> <p>4 impurities could occur in the process as</p> <p>5 it used it, it would have been obliged to</p> <p>6 reveal that in response to this warning</p> <p>7 letter; isn't that right?</p> <p>8 MR. TRISCHLER: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: I mean</p> <p>11 whatever information was shared --</p> <p>12 I mean, whatever information was</p> <p>13 provided should have been shared</p> <p>14 within the warning letter</p> <p>15 response.</p> <p>16 BY MR. HONIK:</p> <p>17 Q. Agreed. Whatever</p> <p>18 information was shared with Mylan should</p> <p>19 have been reported in the response,</p> <p>20 correct?</p> <p>21 A. Again, you're asking me --</p> <p>22 you're asking me for the decisions made</p> <p>23 by another function to prepare the</p> <p>24 response. So I can't speculate as to</p>
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1 what they knew, when they knew it, et
 2 cetera.
 3 Q. No, sir, I'm not asking --
 4 respectfully I'm not asking you any of
 5 that.
 6 I'm asking you as a Mylan
 7 designee on this topic, communications
 8 with the FDA, whether it isn't true that
 9 the company needed to be truthful and
 10 forthcoming based on whatever it learned
 11 before preparing this formal response,
 12 yes or no?
 13 MR. TRISCHLER: Objection to
 14 form. Objection. Asked and
 15 answered.
 16 THE WITNESS: I don't have
 17 any reason to believe that the
 18 response to the warning letter was
 19 not truthful and accurate.
 20 BY MR. HONIK:
 21 Q. I understand and you may yet
 22 have a reason to think that.
 23 But before we get there, do
 24 you agree that if the company came into

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1 possession of information from some
 2 source, a reliable source, that revealed
 3 that nitrosamine impurities was indeed
 4 known and knowable and a potential, that
 5 it should have revealed it to the FDA,
 6 yes or no?
 7 MR. TRISCHLER: Objection to
 8 the form.
 9 THE WITNESS: That's --
 10 that's not a yes-or-no question,
 11 because I don't -- the author of
 12 the document, I don't know what
 13 information they may have had at
 14 the time they wrote the document.
 15 So you're asking me to
 16 speculate what they knew or didn't
 17 know before they made that
 18 response. I can't do that.
 19 BY MR. HONIK:
 20 Q. All right. Well, let's
 21 unpack that proposition a little further.
 22 So if you look at Gomas-2,
 23 sir. Do you have that in front of you?
 24 A. I do.

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1 Q. So you see it's from
 2 Mr. Gomas to Mr. Glover. You know them
 3 both, right?
 4 A. Yes, I do.
 5 Q. And the attachment refer --
 6 the subject is warning letter response,
 7 WL response. Do you see that?
 8 A. Yes.
 9 Q. And you see the date of it
 10 is just four days before Mylan actually
 11 submitted its formal written response to
 12 the FDA warning letter, correct?
 13 A. Yes, it appears to have
 14 preceded it just a few days.
 15 Q. And Dr. Gomas wrote to
 16 Mr. Glover and said, "we have reviewed
 17 this and have few comments. Thank you
 18 for sharing the inputs from Lachman."
 19 So you were aware that the
 20 folks at quality and Dr. Gomas and
 21 Mr. Glover were working on behalf of
 22 Mylan to prepare a response to this
 23 warning letter and the inquiry that we
 24 looked at a moment ago, right?

Page 397

1 A. No, I wasn't aware of who
 2 quality may have been using to prepare
 3 the response.
 4 Q. No, I know that.
 5 A. I was aware -- I was aware
 6 that we had observations and I know that
 7 there was a need to respond to those.
 8 But who quality consulted with, I had no
 9 knowledge of that.
 10 Q. Right. My question is, you
 11 know it now, right?
 12 A. Based on this e-mail
 13 exchange we're looking at, it appears
 14 that they have engaged Lachman to review
 15 the draft.
 16 Q. That's right. It does
 17 appear that they engaged and obtained
 18 inputs from Lachman, because that's what
 19 Dr. Gomas said to Mr. Glover on
 20 November 25, 2019; isn't that right?
 21 MR. TRISCHLER: Objection to
 22 form.
 23 THE WITNESS: Based on this
 24 e-mail exchange, that's what it

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1 appears to say.
2 BY MR. HONIK:
3 Q. And, in fact, it refers to
4 an attachment which is titled Warning
5 Letter Mylan Comments By Aloka.
6 Do you see that?
7 A. Yes.
8 Q. And just two days before
9 that, if you look down at the e-mail
10 thread, you've got Mr. Glover writing to
11 Frances Zipp, lo and behold at Lachman
12 Consultants.
13 Do you see that?
14 MR. TRISCHLER: Objection to
15 form.
16 THE WITNESS: Frances Zipp
17 is an employee of Lachman.
18 BY MR. HONIK:
19 Q. Well, in fact, Frances Zipp
20 is the president and CEO of Lachman,
21 isn't that what it says?
22 A. That appears to be her
23 title, yes.
24 [REDACTED]

Page 399

1 [REDACTED]

Page 400

1 [REDACTED]

Page 401

1 [REDACTED]

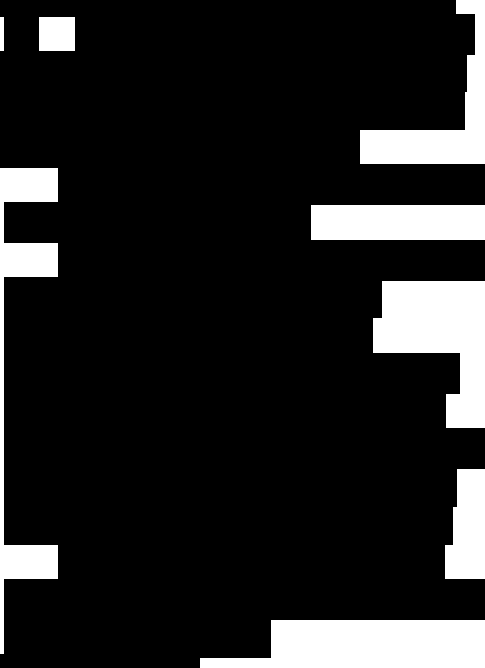
Page 404

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Page 406

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<p>Page 410</p> <p>1 [REDACTED]</p>	<p>Page 412</p> <p>1 [REDACTED]</p>
<p>Page 411</p> <p>1 [REDACTED]</p>	<p>Page 413</p> <p>1 [REDACTED]</p>

<p>Page 414</p> <p>1</p> <p>[REDACTED]</p>	<p>Page 416</p> <p>1</p> <p>[REDACTED]</p>
<p>Page 415</p> <p>1</p> <p>[REDACTED]</p>	<p>Page 417</p> <p>1</p> <p>[REDACTED]</p>

<div>Page 418</div> <div>1</div> <div>[REDACTED]</div>	<div>Page 420</div> <div>1</div> <div>[REDACTED]</div>
<div>Page 419</div> <div>1</div> <div>[REDACTED]</div>	<div>Page 421</div> <div>1</div> <div>[REDACTED]</div>

Page 422

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 BY MR. HONIK:
10 Q. Did Mylan ever supplement or
11 amend or edit its response to
12 Observation 1 of the warning letter from
13 June 20th?
14 A. I don't know what further
15 communications, if any, quality had with
16 the office of compliance.
17 Q. Well, when you were
18 preparing for today, inasmuch as you
19 reviewed this material, have you seen a
20 single piece of paper or document or
21 spoken to anybody that suggests that the
22 response that said Mylan didn't know
23 about the possibility of NDMA or
24 nitrosamines forming and the industry

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1 didn't know, was that ever corrected to
2 reflect the truth, which is that it was
3 well known as your consultant said?
4 MR. TRISCHLER: Objection to
5 the form. Argumentative.
6 Objection. Misstates the record.
7 THE WITNESS: I didn't speak
8 to anyone after reviewing these
9 documents, no.
10 And like I said before, this
11 is a direct communication between
12 quality and FDA.
13 So if there were subsequent
14 communications whether verbal or
15 written, I may not even be aware
16 of those.
17 BY MR. HONIK:
18 Q. Okay. But suffice to say in
19 preparation for today, you haven't seen
20 anything that amended the response to
21 Observation 1 from the warning letter of
22 June 2020, right?
23 A. I'm not aware of anything,
24 but I haven't asked that question. So I

Page 424

1 don't know.
2 Q. All right.
3 MR. HONIK: Why don't we go
4 off the video record, please.
5 THE VIDEOGRAPHER: The time
6 is 5:01 p.m. Off the record.
7 (Short break.)
8 MR. HONIK: Both counsel
9 agree that we are done for the
10 day. We're going resume at
11 9:00 a.m. tomorrow.
12 MR. TRISCHLER: Sure.
13 (Excused.)
14 (Adjourned at approximately
15 5:01 p.m.)
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Page 425

1
2 CERTIFICATE
3
4
5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.
9
10 It was requested before
11 completion of the deposition that the
12 witness, S. WAYNE TALTON, have the
13 opportunity to read and sign the
14 deposition transcript.
15
16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: April 30, 2021
22
23 (The foregoing certification
24 of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

PAGE LINE CHANGE

REASON: _____

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Page 428

ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 429, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

S. WAYNE TALTON DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

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Page 429

LAWYER'S NOTES

PAGE LINE

PAGE	LINE
1	_____
2	_____
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Exhibit 99

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER
12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

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<p style="text-align: right;">Page 627</p> <p>1 ZOOM APPEARANCES: 2 SLACK DAVIS SANGER, LLP 3 BY: JOHN R. DAVIS, ESQ. 4 6001 Bold Ruler Way Suite 100 5 Austin, Texas 78746 (312) 795-8686 6 jdavis@slackdavis.com 7 Representing the Plaintiffs 8 KANNER & WHITELEY, LLC 9 BY: DAVID J. STANOCH, ESQ. 10 701 Camp Street New Orleans, Louisiana 70130 (504) 524-5777 11 dstanoch@kanner-law.com 12 lhilton@kanner-law.com 13 Representing the Plaintiffs 14 GOLOMB & HONIK, P.C. 15 BY: RUBEN HONIK, ESQ. Suite 1900 16 Philadelphia, Pennsylvania 19102 (215) 327-9166 17 ruben@honiklaw.com 18 Representing the Plaintiffs 19 GOLDENBERG LAW, PLLC 20 BY: BEN STELLPFLUG, ESQ. 800 LaSalle Avenue Suite 2150 21 Minneapolis, Minnesota 55402 (612) 436-5028 22 bstellpflug@goldenberglaw.com 23 Representing the Plaintiffs 24</p>	<p style="text-align: right;">Page 629</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 FALKENBERG IVES, LLP 3 BY: MEGAN A. ZMICK, ESQ. 230 W. Monroe Street, Suite 2220 4 Chicago, Illinois 60606 (312) 566-4808 5 Maz@falkenbergives.com 6 Representing the Defendant, Humana 7 NORTON ROSE FULBRIGHT, US, LLP 8 BY: ELLIE NORRIS, ESQ. 9 JACLYN GALLIAN, ESQ. 2200 Rose Avenue, Suite 3600 Dallas, Texas 75201 (214) 855-8000 10 ellie.norris@nortonrosefulbright.com 11 jaclyn.gallian@nortonrosefulbright.com 12 Representing the Defendant, McKesson Corporation 13 CROWELL & MORING, LLP 14 BY: MIMI S. DENNIS, ESQ. 1001 Pennsylvania Avenue, NW Washington, D.C. 20004 (202) 624-2774 15 mdennis@crowell.com 16 Representing the Defendant, Cardinal Health, Inc. 17 CIPRIANI & WERNER, P.C. 18 BY: CAITLIN E. LAWLOR, ESQ. 450 Sentry Parkway, Suite 200 19 Blue Bell, Pennsylvania 19422 (610) 567-0700 20 Clawlor@c-wlaw.com 21 Representing the Defendants, Aurobindo Pharma, USA, Inc. and Aurolife Pharma, LLC 22 23 24</p>
<p style="text-align: right;">Page 628</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 PIETRAGALLO GORDON ALFANO BOSICK & 3 RASPANTI, LLP 4 BY: CLEM C. TRISCHLER, ESQ. JASON M. REEFER, ESQ. MELISSA B. CATELLO, ESQ. 5 One Oxford Centre, 38th Floor Pittsburgh, Pennsylvania 15219 (412) 263-1840 6 cct@pietragallo.com 7 jmr@pietragallo.com 8 mbc@pietragallo.com 9 Representing the Defendant, Mylan Pharmaceuticals, Inc. 10 DUANE MORRIS, LLP 11 BY: KELLY A. BONNER, ESQ. 30 South 17th Street Philadelphia, PA 19103 (215) 979-1158 12 kabonner@duanemorris.com 13 Representing the Defendants, Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston 14 Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC. 15 GREENBERG TRAUIG, LLP 16 BY: BRIAN RUBENSTEIN, ESQ. 17 1717 Arch Street Philadelphia, Pennsylvania 19103 (215) 988-7800 18 rubensteinb@gtlaw.com 19 Representing the Defendants, Teva Pharmaceutical Industries, Ltd., Teva 20 Pharmaceuticals USA, Inc., Actavis LLC, and Actavis Pharma, Inc. 21 22 23 24</p>	<p style="text-align: right;">Page 630</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 3 ALSO PRESENT: 4 5 VIDEOTAPE TECHNICIAN: 6 Kayleigh Duran 7 8 Bradley Matta, Esq. (Mylan) 9 10 Beth Questad - Paralegal (Slack Davis) 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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I N D E X
- - -

Testimony of:
 RICHARD DEREK GLOVER
 By Mr. Davis 638

- - -

E X H I B I T S
- - -

NO.	DESCRIPTION	PAGE
13 Mylan		
14 PL-Glover-70 Patient Information	Valsartan Tablets	646
15 USP		
16 MYLAN-MDL2875-00035696-01		
17 Mylan		
18 PL-Glover-71 Way Back Machine	Mylan Website Resources	650
19 2/13/14		
20 Mylan		
21 PL-Glover-72 Way Back Machine	Mylan Website	651
22 2/13/14	Why Generics?	
23 2/13/14		
24		

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E X H I B I T S (Cont'd.)
- - -

NO.	DESCRIPTION	PAGE
5 Mylan		
6 PL-Glover-78 Sam's Club General	Merchandise Supplier	700
7 Agreement		
8 WALMART0000597-07		
9 Mylan		
10 PL-Glover-79 PowerPoint	Prescription Product	703
11 Supplier Requirements		
12 WALMART00000001		
13 Mylan		
14 PL-Glover-80 E-mail Thread	12/26/18	730
15 Subject, Information		
16 MYLAN-MDL2875-00460527-28		
17 Mylan		
18 PL-Glover-81 EU Referral Under	Article 31	732
19 MYLAN-MDL2875-00460529-31		
20 Mylan		
21 PL-Glover-82 Mylan Technical/	Quality Agreement	743
22 Mylan & Lantech		
23 MYLAN-MDL2875-00698731		
24 Mylan		
PL-Glover-83 E-mail Thread	11/30/18	752
MYLAN-MDL2875-00702457		
-001-11		

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E X H I B I T S (Cont'd.)
- - -

NO.	DESCRIPTION	PAGE
6 Mylan		
7 PL-Glover-73 Way Back Machine	Mylan Website	657
8 Our Mylan Is Your		
9 Mylan		
10 2/13/14		
11 Mylan		
12 PL-Glover-74 E-mail Thread	5/20/20	671
13 Subject, Discussion on		
14 Nitrosamine General		
15 Advice Letter		
16 MYLAN-MDL2875-00264918-19		
17 Mylan		
18 PL-Glover-75 General Advice	Letter	672
19 2/13/20		
20 MYLAN-MDL2875-00264920		
21 Mylan		
22 PL-Glover-76 AmerisourceBergen	Exhibit A	686
23 Continuing Guaranty		
24 And Indemnification		
ABC-MDL2875-00000248		
21 Mylan		
22 PL-Glover-77 Walgreens/	AmerisourceBergen	696
23 Pharmaceutical		
24 Purchase and Distribution		
Agreement		
Execution Copy		
WALGREENS0000782-14		

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E X H I B I T S (Cont'd.)
- - -

NO.	DESCRIPTION	PAGE
6 Mylan		
7 PL-Glover-84 E-mail Thread	12/6/14	759
8 Subject, Inquiry		
9 To Valsartan from PMDA		
10 MYLAN-MDL2875-00255224-27		

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- - -
 PREVIOUSLY MARKED
 EXHIBITS
 - - -

NO.	DESCRIPTION	PAGE
6	Mylan	
7	PL-Glover-2 Amended Notice	662
8	Of Deposition	
9		
10	Mylan	
11	PL-Glover-54 Warning Letter	668
12	320-20-06	
13	11/5/19	
14	MYLAN-MDL2875-00345711	
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		

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- - -

THE VIDEOGRAPHER: We are now on the record.

My name is Kayleigh Duran, a videographer for Golkow Litigation Services.

Today's date is April 16th, 2021, and the time is 9:26 a.m.

This deposition is being held by remote Zoom in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation.

The deponent today is Derek Glover, Volume III.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All appearances are noted on the stenographic record and the witness has been previously sworn in.

- - -

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- - -
 DEPOSITION SUPPORT INDEX
 - - -

5	Direction to Witness Not to Answer
6	PAGE LINE
7	None.
8	Request for Production of Documents
9	PAGE LINE
10	None.
11	Stipulations
12	PAGE LINE
13	None.
14	Questions Marked
15	PAGE LINE
16	None.
17	
18	
19	
20	
21	
22	
23	
24	

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... RICHARD DEREK GLOVER, having been previously sworn, was examined and testified as follows:

- - -

THE VIDEOGRAPHER: Counsel, you may proceed.

- - -

CONTINUED EXAMINATION

- - -

BY MR. DAVIS:

Q. Good morning, Mr. Glover. How are you today?

A. Good morning. I'm fine.

Thank you.

Q. Good. Good. So it's been a while since we talked last, so I wanted to sort of get filled in on who you talked to and met with since our last session, which I believe was March 12th.

So between March 12th and today, have you met with counsel at all regarding preparing for today's deposition?

A. I have.

Page 639	Page 641
<p>1 Q. About how many times?</p> <p>2 A. I attended two of Dr. Gomas'</p> <p>3 prep sessions for about an hour, and then</p> <p>4 I met yesterday with counsel for a couple</p> <p>5 of hours.</p> <p>6 Q. Okay. So two separate</p> <p>7 sessions for Dr. Gomas, each lasting</p> <p>8 about an hour?</p> <p>9 A. Well, his sessions were</p> <p>10 longer, but I was only able to attend for</p> <p>11 about an hour.</p> <p>12 Q. Okay. And counsel was</p> <p>13 present the entire time during those prep</p> <p>14 sessions with Dr. Gomas?</p> <p>15 A. Yeah.</p> <p>16 Q. Okay. And then you said how</p> <p>17 long -- the meeting yesterday with</p> <p>18 counsel, how long did that take?</p> <p>19 A. It was a couple hours, two</p> <p>20 or three hours.</p> <p>21 Q. Okay. Did you review</p> <p>22 documents in this last meeting?</p> <p>23 A. We did.</p> <p>24 Q. About how many documents?</p>	<p>1 dose customers, other downstream entities</p> <p>2 regarding Mylan's products, the quality,</p> <p>3 purity, contamination issues, et cetera,</p> <p>4 relating to Mylan's API and finished dose</p> <p>5 products.</p> <p>6 Are you familiar with those</p> <p>7 topics?</p> <p>8 A. Generally, yes.</p> <p>9 Q. Okay. What did you do to</p> <p>10 prepare yourself to testify on those</p> <p>11 topics in particular?</p> <p>12 A. I think I can only think of</p> <p>13 maybe seeing a few e-mails throughout</p> <p>14 prep sessions, but other than that,</p> <p>15 nothing.</p> <p>16 Q. Okay. Are you familiar that</p> <p>17 Mylan has three ANDA applications</p> <p>18 approved relating to valsartan products?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And just for</p> <p>21 reference, those would be amlodipine</p> <p>22 valsartan with ANDA Number 090483,</p> <p>23 correct?</p> <p>24 A. That sounds right.</p>
Page 640	Page 642
<p>1 A. A handful.</p> <p>2 Q. Were they previously marked</p> <p>3 exhibits? Did they have yellow stickers</p> <p>4 on them?</p> <p>5 A. I don't know. They were</p> <p>6 being presented electronically on a</p> <p>7 screen.</p> <p>8 Q. Okay. How about -- aside</p> <p>9 from the prep sessions for Dr. Gomas and</p> <p>10 for yourself for today, did you meet with</p> <p>11 anyone else at all regarding your</p> <p>12 testimony today?</p> <p>13 A. No.</p> <p>14 Q. Okay. Have you -- did you</p> <p>15 endeavor to do more work to prepare</p> <p>16 yourself for the 30(b)(6) topic that</p> <p>17 you're testifying on?</p> <p>18 A. No, not really.</p> <p>19 Q. Okay. I'm going to start</p> <p>20 with a set of three or four topics that</p> <p>21 we haven't touched on yet. Those are</p> <p>22 Topics 36 through 39, which relate</p> <p>23 generally to Mylan's oral and written</p> <p>24 communications to API customers, finished</p>	<p>1 Q. Okay. And then valsartan</p> <p>2 HCTZ, which is ANDA Number 078020?</p> <p>3 A. I believe you. I don't have</p> <p>4 the ANDA numbers memorized. But yes, the</p> <p>5 product name sounds right.</p> <p>6 Q. Okay. And then finally</p> <p>7 valsartan, plain valsartan, ANDA 090866,</p> <p>8 does that sound right to you?</p> <p>9 A. It does.</p> <p>10 Q. Okay. So for every</p> <p>11 valsartan-containing pill that was sold</p> <p>12 in the U.S., Mylan sold those pills</p> <p>13 pursuant to one of those three ANDAs,</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And I guess the converse of</p> <p>17 that is Mylan didn't sell any products</p> <p>18 that contained valsartan not pursuant to</p> <p>19 any one of those three approved ANDAs,</p> <p>20 correct?</p> <p>21 A. Not to my knowledge, no.</p> <p>22 Q. Okay. And when Mylan sold</p> <p>23 valsartan-containing products in the U.S.</p> <p>24 pursuant to those ANDAs, it always</p>

<p>Page 643</p> <p>1 referred to those products by their 2 approved generic names, correct? 3 And what I mean by that is 4 amlodipine valsartan, valsartan HCTZ, or 5 valsartan, correct? 6 A. I believe so, yes. 7 Q. Okay. And those products 8 were labeled in the FDA-approved manner 9 as approved in the respective ANDA 10 application? 11 A. Yes. 12 Q. And that includes 13 distribution of package inserts and 14 patient information leaflets? 15 A. Whatever is approved in the 16 application, yes. 17 Q. Okay. Are you familiar with 18 the package insert for any of the three 19 valsartan ANDAs? 20 A. No. 21 Q. Have you ever looked at it? 22 A. I have not. 23 Q. Okay. What about the 24 patient information leaflet?</p> <p>Page 644</p> <p>1 A. I don't believe I've looked 2 at it. 3 Q. Okay. Are you familiar with 4 what a patient information leaflet is 5 generally? 6 A. Yes. 7 Q. Okay. What is it? 8 A. My understanding is the 9 patient leaflet is a list of instructions 10 or warnings or just general facts about 11 the drug. 12 Q. And it's directed at the 13 patient, correct? 14 A. Yes. 15 Q. Okay. And drafted by Mylan? 16 A. I would assume. I'm not 17 a -- some expert on the topic, but I 18 believe we write it in conjunction with 19 the health authority. I think it's part 20 of the label package that gets reviewed 21 by FDA. 22 Q. Correct. But Mylan submits 23 its draft patient information leaflet to 24 the FDA for approval, correct?</p>	<p>Page 645</p> <p>1 A. Yeah. I think the only 2 thing that I wouldn't want to mislead in 3 the sense that I think labeling as a 4 whole has sort of a brand influence as 5 well. 6 So when FDA reviews it, they 7 generally reflect on the brand content 8 and then tries to match as much of that 9 information as they can with the brand 10 product. 11 Q. Okay. Nevertheless, Mylan, 12 you know, with what you said is, you 13 know, included in that, Mylan does submit 14 a Mylan package insert and a Mylan 15 patient information leaflet for its 16 valsartan-containing products as part of 17 those ANDA applications, correct? 18 MR. TRISCHLER: Objection. 19 Asked and answered. 20 Objection beyond the scope. 21 Objection. Lack of 22 foundation. 23 THE WITNESS: Yeah, as I 24 mentioned, I think Mylan would</p> <p>Page 646</p> <p>1 issue the first draft and then it 2 is routinely back and forth with 3 FDA as FDA pushes the language 4 towards continuity with the brand 5 product. 6 MR. DAVIS: I'm marking Tab 7 89 as Exhibit, I believe, 70. I 8 think we're starting at 70. 9 (Document marked for 10 identification as Exhibit 11 PL-Glover-70.) 12 THE WITNESS: Okay. 13 MR. DAVIS: Does this -- 14 MR. TRISCHLER: He has 15 the -- he has the document, John. 16 MR. DAVIS: Okay. Sure. 17 BY MR. DAVIS: 18 Q. Taking a quick look at it. 19 It's six pages. Do you see that it says 20 "Patient Information" at the top of the 21 first substantive page? 22 A. Yes. 23 Q. Okay. And do you see that 24 Mylan's logo and sort of some</p>
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1 document-identifying information is on
2 the last page at the end?
3 A. Yes.
4 Q. Does this look to you to be
5 the Mylan patient information leaflet for
6 valsartan?
7 A. It looks like it, yes.
8 Q. Okay. Take a look at the
9 bottom of Page 5, "What Are the
10 Ingredients in Valsartan Tablets?"
11 A. Okay.
12 Q. It says, "Active ingredient
13 valsartan."
14 Do you see that?
15 A. Yes.
16 Q. And then it lists a number
17 of inactive ingredients as well?
18 A. Yes.
19 Q. And would you agree with me
20 that nitrosamines are listed nowhere in
21 this patient information leaflet,
22 including this "What Are the Ingredients
23 in Valsartan Tablets?" section?
24 MR. TRISCHLER: Objection.

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1 Beyond the scope.
2 THE WITNESS: It does not
3 say that or any other impurity
4 names, nor would it.
5 BY MR. DAVIS:
6 Q. Okay. Would you agree that
7 nitrosamines are technically an active
8 ingredient?
9 MR. TRISCHLER: Objection to
10 form.
11 THE WITNESS: No.
12 BY MR. DAVIS:
13 Q. They have an effect on
14 people's bodies, correct, when they
15 ingest them?
16 MR. TRISCHLER: Objection.
17 Foundation. Objection. Beyond
18 the scope.
19 THE WITNESS: I'm not
20 qualified to answer on whether
21 nitrosamine has an effect or at
22 what levels. I'm not a
23 toxicologist.
24 BY MR. DAVIS:

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1 Q. Okay. Would you agree that
2 nitrosamines are not listed in the
3 package insert for any of Mylan's
4 valsartan-containing products?
5 MR. TRISCHLER: Objection.
6 Foundation.
7 Objection. Beyond the
8 scope.
9 THE WITNESS: I haven't
10 reviewed all the documents. I
11 would wager that it's not listed.
12 It's not common to list any -- any
13 impurities of any type in
14 products. That's not part of the
15 labeling process.
16 BY MR. DAVIS:
17 Q. Right. And you would also
18 agree that nitrosamines are nowhere in
19 any of the labeling information for
20 Mylan's valsartan-containing products,
21 right?
22 MR. TRISCHLER: Same
23 objections.
24 THE WITNESS: Again, I'm not

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1 a regulatory expert, but I don't
2 believe so.
3 BY MR. DAVIS:
4 Q. Okay.
5 MR. DAVIS: I'm marking Tab
6 104 as Exhibit 71.
7 (Document marked for
8 identification as Exhibit
9 PL-Glover-71.)
10 MR. TRISCHLER: He has the
11 document, John.
12 BY MR. DAVIS:
13 Q. I'll represent to you this
14 is a screen shot of Mylan's website from,
15 I guess, somewhere between 2014 and 2015.
16 Are you familiar with the
17 Way Back Machine, Mr. Glover?
18 A. No, I'm not.
19 Q. Okay. It's essentially an
20 internet archive where it goes through
21 and collects websites as they exist at a
22 period of time. It's like a time capsule
23 for the internet, basically.
24 So this is Mylan's website.

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1 As you can see, the URL is
2 mylan.com.
3 Do you see that up in the
4 top there on Page 1?
5 A. Yes.
6 Q. Okay. And then you'll see a
7 resource section for patients.
8 Do you see that?
9 A. I do.
10 Q. Okay. And then on the
11 second page, tracking down from patients,
12 you'll see that there's three links, one
13 says, "Why generics?" One says, "Mylan
14 quality," and one says, "Health
15 information."
16 Do you see that?
17 A. Yes.
18 Q. Okay.
19 MR. DAVIS: I'm going to
20 mark Tab 105 as Exhibit 72.
21 (Document marked for
22 identification as Exhibit
23 PL-Glover-72.)
24 THE WITNESS: Okay. I have

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1 it.
2 BY MR. DAVIS:
3 Q. Okay. You'll see that the
4 header on this is, "Why generic?"
5 This is the link under the,
6 "Why generics?" tab under Patient
7 Resources we saw on Exhibit 71.
8 Does that look correct to
9 you?
10 A. Yes.
11 Q. Okay. So would you agree
12 that Exhibit 72 is a consistent statement
13 that Mylan is directing to consumers,
14 i.e., patients of Mylan's product?
15 A. Yes.
16 Q. Okay. If you go down to the
17 second page, you'll see a section on
18 bioequivalence.
19 Do you see that?
20 A. I see the word
21 "bioequivalence," yes.
22 Q. To the right of that --
23 A. I see at the top of the page
24 also -- you're talking about the very top

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1 of the page?
2 Q. Yes, sir, I am. So you'll
3 see there's a section on bioequivalence
4 and then some text that Mylan puts in
5 there, "To gain FDA approval," and then
6 it goes on.
7 Do you see that?
8 A. Yes.
9 Q. Okay. Mylan says there
10 that, "Bioequivalence means generic and
11 brand name medicines are the same in the
12 following ways," and then it lists some
13 ways that they are the same, correct?
14 A. Yes.
15 Q. Okay. And that includes --
16 you know, the first thing they list is
17 active ingredient, correct?
18 A. Yes.
19 Q. Okay. Expected safety and
20 efficacy is another one?
21 A. Yep.
22 Q. Okay. And FDA evaluation of
23 manufacturing facilities, correct?
24 A. Yep.

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1 Q. Okay. So what is this? Is
2 Mylan trying to convey here that Mylan's
3 generic products are indeed bioequivalent
4 to their brand counterparts?
5 MR. TRISCHLER: Objection to
6 form. Beyond the scope.
7 THE WITNESS: I don't know
8 exactly what the intention of the
9 web page is. I didn't build it.
10 I wasn't a part of it.
11 BY MR. DAVIS:
12 Q. Well, you would agree that
13 this is a communication from Mylan
14 directed at patients of Mylan's product,
15 correct?
16 A. Appears to be, yes.
17 Q. Okay. And you're designated
18 on that topic, are you not?
19 MR. TRISCHLER: No, he's not
20 designated on every communication
21 from Mylan to patients concerning
22 any subject under the universe.
23 It is a misstatement of the
24 scope of the designation, which is

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1 why I objected to the scope of the
2 question.
3 MR. DAVIS: Well, Topic 38,
4 Clem, says Mylan's oral and
5 written statements to consumers
6 with regard to contents and purity
7 of Mylan's API.
8 MR. TRISCHLER: I don't see
9 anything in here that has to do
10 with Mylan's valsartan API, John,
11 which is why I objected to the
12 scope.
13 MR. DAVIS: Okay. Well, I
14 disagree with that, but we can --
15 MR. TRISCHLER: Well, show
16 me where the word "valsartan"
17 appears in Exhibit 71?
18 MR. DAVIS: Does this --
19 BY MR. DAVIS:
20 Q. Mr. Glover, is Mylan
21 attempting to except valsartan from what
22 it's conveying here to consumers about
23 its product being bioequivalent to their
24 reference-listed drug brand counterparts?

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1 MR. TRISCHLER: Objection to
2 form.
3 Objection. Beyond the
4 scope.
5 THE WITNESS: Again, I
6 didn't build the web page. I have
7 no idea what the scope or extent
8 of the statement is on the web
9 page.
10 BY MR. DAVIS:
11 Q. It doesn't say -- the text
12 here on Exhibit 72 does not say, "With
13 the exception of valsartan API, generic
14 medicines must be bioequivalent," does
15 it?
16 MR. TRISCHLER: Objection to
17 the form.
18 Objection. Beyond the scope
19 of the designation.
20 You can answer if you can.
21 THE WITNESS: It doesn't say
22 what you said, no.
23 MR. DAVIS: I'm going to
24 mark Tab 106 as Exhibit 73.

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1 (Document marked for
2 identification as Exhibit
3 PL-Glover-73.)
4 MR. TRISCHLER: Was there a
5 72, John?
6 MR. DAVIS: Yeah, that
7 was -- that was the last one we
8 looked at, the bioequivalence one,
9 Tab 105.
10 MR. TRISCHLER: Oh, I'm
11 sorry. I'm sorry.
12 THE WITNESS: Okay.
13 BY MR. DAVIS:
14 Q. Mr. Glover, you'll see,
15 again, this is from the Way Back Machine,
16 mylan.com.
17 The first couple of pages
18 are some hyperlinks to videos. And then
19 you'll see on Page 3 where the text
20 starts, and it says -- starts with,
21 "Mylan quality."
22 Do you see that?
23 A. I'm sorry. Are we still on
24 Page 1? I got lost.

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1 Q. I'm sorry. Yeah, so Page 1
2 and 2 and 3 appear to be some hyperlinks
3 to videos that are reflected in this
4 printout of the website.
5 And then you'll see a Page 3
6 where substantive text starts with,
7 "Mylan quality."
8 Do you see that?
9 A. Yes, I do.
10 Q. Okay. And if you refer back
11 to Exhibit 71, you'll see, again, that
12 that's a hyperlink under the Patient
13 Resource portion of Mylan's website as it
14 existed at this time, correct?
15 A. I believe you.
16 Q. Okay. And so would you
17 agree that, again, this Exhibit 73 is a
18 resource directed at patients regarding
19 Mylan quality?
20 MR. TRISCHLER: Objection to
21 the form.
22 Objection. Beyond the
23 scope.
24 THE WITNESS: My guess is

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1 that it's available to anybody who
2 wants to read it.
3 BY MR. DAVIS:
4 Q. Okay. You'll see a quote
5 from Robert Corey there. Who is Robert
6 Corey?
7 A. He's the executive chairman
8 of the board.
9 Q. Does he still serve in that
10 role?
11 A. I'm not exactly sure. I
12 know he's chairman of the board, but he
13 may have another title also.
14 Q. Okay. He says there, "We
15 have one global quality standard because
16 we know where our priorities are. It all
17 starts and ends with you."
18 Do you read the "you" there
19 as being the patient?
20 MR. TRISCHLER: Objection to
21 form.
22 Objection. Beyond the
23 scope.
24 THE WITNESS: I'd be purely

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1 speculating. I'm guessing it's
2 anyone who's reading the message.
3 BY MR. DAVIS:
4 Q. Okay. And that message, as
5 you testified, was directed towards
6 patients as a patient resource, correct?
7 MR. TRISCHLER: Objection.
8 Misstates testimony.
9 THE WITNESS: I think it's
10 everyone who reads it. So
11 patients are a part of that pool.
12 I'm guessing there's more than
13 just patients that read.
14 BY MR. DAVIS:
15 Q. Well, sure. As you saw,
16 this particular page falls -- or fell
17 under the Patient Resource section of
18 Mylan's website as it existed at the
19 time, correct?
20 A. It does, but I don't -- I'm
21 guessing. Again, I didn't build the web
22 page. But I'm sure you don't have to
23 prove you're a patient to go to click on
24 the link. So I'm guessing anyone who

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1 wants to read it, can read it.
2 Q. Okay. And you'll see to the
3 right there, there's a little cut-out
4 paragraph, "Why generics?" And it says,
5 "Low cost and high quality."
6 Do you see that?
7 A. Yes.
8 Q. Okay. What does high
9 quality mean to you?
10 A. High quality means that it
11 meets all the standards of
12 pharmaceuticals within its intended
13 marketplace according to the health
14 authorities.
15 Q. Okay. Did Mylan at all
16 relevant times, prior to the recall, hold
17 out the valsartan-containing products as
18 being non-adulterated and in compliance
19 with the FDCA requirements?
20 MR. TRISCHLER: Objection to
21 the form. Objection to the extent
22 that it calls for a conclusion of
23 law.
24 MR. DAVIS: I'm asking what

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1 Mylan held out, not whether in
2 fact that was the case.
3 THE WITNESS: That didn't
4 come out to me in your question.
5 Can you explain that to me?
6 BY MR. DAVIS:
7 Q. Sure. As you saw, you --
8 yeah, sorry to cut you off there. I
9 didn't mean to do that.
10 I'm referring -- these
11 questions are in the context of Topics 36
12 through 39. Do you have those in front
13 of you?
14 A. No.
15 Q. Let me go back to --
16 MR. DAVIS: I'm going to
17 publish on my screen Plaintiff
18 Glover-2.
19 (Previously marked
20 PL-Glover-2.)
21 BY MR. DAVIS:
22 Q. Do you see this, Mr. Glover?
23 A. Yeah.
24 Q. Do you recognize this from

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1 the first day of your deposition? It's
2 your -- the amended deposition notice.
3 A. Yes.
4 Q. Okay. Do you see Topics 36
5 through 39 there?
6 A. Okay. Yes.
7 Q. Okay. And these are the
8 topics that you testified earlier you
9 didn't really do anything to prepare for?
10 MR. TRISCHLER: Objection to
11 the form. Misstates testimony.
12 THE WITNESS: I believe I
13 said I read a few e-mails.
14 BY MR. DAVIS:
15 Q. And that was it, correct?
16 A. Yes.
17 Q. Okay. What were those
18 e-mails?
19 A. I don't have them memorized.
20 Q. Okay. Who were they -- do
21 you recall who the e-mails were from and
22 to?
23 A. I don't.
24 Q. Okay. How about when they

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1 were written, do you remember that?
2 A. I don't. It was various
3 years.
4 Q. Okay. Pre-recall e-mails or
5 post-recall e-mails?
6 A. Both.
7 Q. Okay. So do you see here
8 that you're designated for, you know,
9 "Mylan's oral and written communications
10 to its API customers or other downstream
11 entities, including wholesalers,
12 retailers, consumers, third-party payors,
13 regarding quality, purity, or
14 contamination issues related to Mylan
15 API"?
16 A. I do, yes.
17 Q. And then same thing for
18 finished dose customers, 37?
19 A. Yes.
20 Q. And then 38 is sort of all
21 inclusive. "Mylan's oral and written
22 statements to finished dose
23 manufacturers, wholesalers, retailers,
24 and consumers with regard to the contents

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1 and purity of Mylan's valsartan API"?
2 A. Yes.
3 Q. Okay. And 39 is the same
4 thing for finished dose?
5 A. Yes.
6 MR. TRISCHLER: Just let the
7 record be clear -- I may have
8 missed it, John, but when you read
9 36 and 37, I think you may have
10 left out the word "valsartan." I
11 don't know whether that was
12 intentional or inadvertent, or
13 maybe I just didn't hear it.
14 But I just wanted to be
15 clear that's what the designation
16 related to.
17 MR. DAVIS: Sure, yes, and
18 that's fine. Although, you know,
19 I'll say that, you know, to the
20 extent that, you know, valsartan
21 is included in a more generalized
22 statement about Mylan's products,
23 you know, that that's something
24 that's fair game, in my opinion,

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1 for corporate designee testimony
2 under these topics.
3 MR. TRISCHLER: And I've not
4 prevented you from asking any
5 question. But I disagree -- we
6 may disagree as to what the scope
7 of the designation is.
8 MR. DAVIS: Okay.
9 BY MR. DAVIS:
10 Q. Okay. So back to my
11 question, Mr. Glover. Did Mylan at all
12 times prior to recall hold out its
13 valsartan API and finished dose as being
14 non-adulterated, for example?
15 MR. TRISCHLER: Objection to
16 form. Objection to the extent
17 that it calls for a legal opinion
18 or conclusion.
19 You may answer.
20 THE WITNESS: I don't know
21 what "hold out" means, and I'm not
22 really qualified to answer that
23 question.
24 Mylan manufactured its

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1 product in accordance with the
2 registered specs and methods. And
3 that was our mission throughout
4 the time that you're referring.
5 BY MR. DAVIS:
6 Q. Did Mylan make any oral or
7 written statements to any of the
8 following finished dose manufacturers,
9 wholesalers, retailers, or consumers that
10 its products were either adulterated or
11 not-adulterated for valsartan API or
12 finished dose?
13 A. I'm not aware of any
14 statements in either direction regarding
15 those words, no.
16 Q. What about the same question
17 with regard to Mylan's API and finished
18 dose valsartan being manufactured in
19 compliance with cGMPs?
20 A. In compliance with cGMPs,
21 I'm not sure either. Yeah, I'm not sure.
22 Q. Does Mylan think an
23 adulterated product can be, quote, "high
24 quality"?

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1 MR. TRISCHLER: Objection to
2 the form. Argumentative.
3 THE WITNESS: Again, I'm not
4 qualified to even define
5 adulteration. I'm not a policy
6 lawyer or regulatory lawyer.
7 BY MR. DAVIS:
8 Q. Well, the FDA has told Mylan
9 that its valsartan API and finished dose
10 is adulterated if it contains
11 nitrosamines, correct?
12 MR. TRISCHLER: Objection to
13 the form.
14 THE WITNESS: I'm not aware
15 of that either. I'm not aware
16 that statement was made.
17 BY MR. DAVIS:
18 Q. Do you have Plaintiff
19 Glover-54 in front of you?
20 (Previously marked
21 PL-Glover-54.)
22 MR. DAVIS: Clem, that was
23 in the documents that I sent over
24 this morning.

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1 I can publish it as well.
2 Either way.
3 MR. TRISCHLER: No, if you
4 give -- if you give me a minute, I
5 can get it.
6 Exhibit 54?
7 MR. DAVIS: Plaintiff Glover
8 Exhibit 54.
9 BY MR. DAVIS:
10 Q. Do you recall this being the
11 Unit 8 warning letter dated November 5,
12 2019, Mr. Glover?
13 A. Yes, I do.
14 Q. And you would agree, would
15 you not, that Unit 8 is still under
16 "official action indicated" status,
17 correct?
18 A. They are.
19 Q. Okay. And do you see on the
20 first page, the cover letter, the
21 paragraph that reads, "Because your
22 methods, facilities, or controls for
23 manufacturing, processing, packing, or
24 holding do not conform to cGMP, your API

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1 are adulterated"?
2 Do you see that?
3 A. I do. Yeah, I see it.
4 Q. Okay. Does that remind you
5 that the FDA has determined that Mylan's
6 API coming from Unit 8 is adulterated?
7 MR. TRISCHLER: Objection to
8 form.
9 THE WITNESS: It reminds me
10 FDA took that position.
11 It doesn't mean we agree
12 with it, and it doesn't mean that
13 there isn't ongoing discussions
14 with FDA regarding everything in
15 this warning letter.
16 So -- but, yeah, it reminds
17 me that FDA did write this.
18 BY MR. DAVIS:
19 Q. Okay. And it's the FDA's
20 determination that matters, correct, not
21 what Mylan disagrees or agrees with on
22 determinations of whether a product is
23 adulterated under the regs, correct?
24 MR. TRISCHLER: Objection to

<p style="text-align: right;">Page 671</p> <p>1 form.</p> <p>2 THE WITNESS: I'm not a</p> <p>3 regulatory lawyer. I'm not</p> <p>4 exactly sure who has final say. I</p> <p>5 know the Department of Justice</p> <p>6 also gets involved in these</p> <p>7 situations in certain</p> <p>8 circumstances.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Has DOJ gotten involved in</p> <p>11 this Unit 8 situation?</p> <p>12 A. Not at this point, no.</p> <p>13 Q. Are you familiar with an FDA</p> <p>14 general advice letter saying that if</p> <p>15 nitrosamines are detected above the</p> <p>16 interim threshold, that that</p> <p>17 automatically means the product is</p> <p>18 adulterated?</p> <p>19 A. I'm not familiar with it,</p> <p>20 no.</p> <p>21 MR. DAVIS: I'm marking</p> <p>22 Tab 310 as Exhibit 74.</p> <p>23 (Document marked for</p> <p>24 identification as Exhibit</p>	<p style="text-align: right;">Page 673</p> <p>1 seen before?</p> <p>2 A. It looks vaguely familiar,</p> <p>3 yes.</p> <p>4 Q. Okay. Do you see on the</p> <p>5 third page -- or actually, really,</p> <p>6 it's -- if you use the numbering in the</p> <p>7 top left, it'll be Page 2 of the letter.</p> <p>8 A. Okay.</p> <p>9 Q. And Then the second-to-last</p> <p>10 paragraph, it reads, "If n-nitrosamines</p> <p>11 are detected in a drug product above the</p> <p>12 ADI in any distributed batch of DP within</p> <p>13 the labeled expiration date, the drug is</p> <p>14 considered to be adulterated and may also</p> <p>15 be misbranded under Sections 501 and 502</p> <p>16 of the FDCA respectively."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Does that remind you</p> <p>20 that the FDA's position is that if</p> <p>21 nitrosamines are present in drug product</p> <p>22 above the acceptable daily intake interim</p> <p>23 limits, that the FDA considers that drug</p> <p>24 product to be adulterated?</p>
<p style="text-align: right;">Page 672</p> <p>1 PL-Glover-74.)</p> <p>2 THE WITNESS: Okay. I have</p> <p>3 it.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. You'll see that this is an</p> <p>6 e-mail among a number of individuals at</p> <p>7 Mylan, including several that report to</p> <p>8 you, including for example, Dr. Gomas.</p> <p>9 Do you see him on there?</p> <p>10 A. I do.</p> <p>11 Q. Okay. And the attachment</p> <p>12 is, "Nitrosamine general advice letter,</p> <p>13 February 2020.pdf."</p> <p>14 Do you see that?</p> <p>15 A. I see a reference to it,</p> <p>16 yes.</p> <p>17 MR. DAVIS: Okay. I am</p> <p>18 marking Tab 311 as Exhibit 75.</p> <p>19 (Document marked for</p> <p>20 identification as Exhibit</p> <p>21 PL-Glover-75.)</p> <p>22 THE WITNESS: I have it.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Is this a letter that you've</p>	<p style="text-align: right;">Page 674</p> <p>1 MR. TRISCHLER: Objection to</p> <p>2 form. Vague as to time.</p> <p>3 THE WITNESS: I understand</p> <p>4 that as of February 20th or</p> <p>5 whenever this was issued, they</p> <p>6 took this position, yes, I</p> <p>7 understand that's their position</p> <p>8 now.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Do you have any reason to</p> <p>11 believe that was not the FDA's position</p> <p>12 in 2018 when it first learned of</p> <p>13 nitrosamine contamination in valsartan</p> <p>14 API and finished dose product?</p> <p>15 A. Well, prior to that point,</p> <p>16 they hadn't established any limits or</p> <p>17 expectations, and the established limits</p> <p>18 are what we release product against.</p> <p>19 These are new limits established after</p> <p>20 the investigations were completed. And</p> <p>21 now they've established a new criteria</p> <p>22 for distribution.</p> <p>23 Q. Recalls happened back in</p> <p>24 2018, did they not?</p>

<p style="text-align: right;">Page 675</p> <p>1 A. Yes.</p> <p>2 Q. And the FDA insisted on</p> <p>3 those recalls happening, correct?</p> <p>4 A. No. FDA doesn't insist</p> <p>5 recalls. FDA works with the industry,</p> <p>6 and the industry takes voluntary action.</p> <p>7 Q. Are you --</p> <p>8 A. They don't have jurisdiction</p> <p>9 to demand recalls. They can do seizures.</p> <p>10 Q. Are you familiar with any</p> <p>11 FDA communications with Mylan around late</p> <p>12 2018 where the FDA conveyed an</p> <p>13 expectation that Mylan would recall its</p> <p>14 valsartan API and finished dose for</p> <p>15 nitrosamine contamination?</p> <p>16 A. I mean, they're allowed to</p> <p>17 do that. But they don't demand recalls.</p> <p>18 They work with the industry and make</p> <p>19 suggestions. But the industry takes</p> <p>20 voluntary action as recall. And that's</p> <p>21 what we did. We did a voluntary recall.</p> <p>22 Q. Correct. And so had Mylan</p> <p>23 not done a voluntary recall, you don't</p> <p>24 know whether the FDA would have invoked a</p>	<p style="text-align: right;">Page 677</p> <p>1 and finished dose were manufactured under</p> <p>2 cGMPs sufficient to assure the quality of</p> <p>3 the product?</p> <p>4 A. Again, I'm not certain of</p> <p>5 any public statements or, you know, any</p> <p>6 issuance of any statements like that, no.</p> <p>7 Q. Is there something</p> <p>8 inconsistent in your mind about saying</p> <p>9 that a product is high quality,</p> <p>10 meaning -- that that same product that's</p> <p>11 high quality could also be adulterated?</p> <p>12 MR. TRISCHLER: Objection to</p> <p>13 form. Argumentative.</p> <p>14 Objection to the extent that</p> <p>15 it calls for a legal conclusion</p> <p>16 and opinion.</p> <p>17 You can answer if you can.</p> <p>18 THE WITNESS: No, I don't</p> <p>19 find anything contradictory about</p> <p>20 what you just said. I don't know</p> <p>21 how you even put that together.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. I guess -- let me rephrase</p> <p>24 the question.</p>
<p style="text-align: right;">Page 676</p> <p>1 seizure authority, do you?</p> <p>2 A. I do not.</p> <p>3 Q. Thank you. So I think</p> <p>4 before we went off on that little</p> <p>5 diversion, I was asking whether -- and</p> <p>6 again, this relates to Topics 38 and 39,</p> <p>7 whether Mylan conveyed to finished dose</p> <p>8 manufacturers, wholesalers, retailers or</p> <p>9 consumers that its valsartan API or</p> <p>10 finished dose products were not</p> <p>11 adulterated?</p> <p>12 A. Yeah, again, my answer --</p> <p>13 MR. TRISCHLER: Objection.</p> <p>14 Asked and answered.</p> <p>15 THE WITNESS: -- is the</p> <p>16 same.</p> <p>17 I'm not aware of any</p> <p>18 communications with those types of</p> <p>19 words in them from -- from our</p> <p>20 company.</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. And is your answer the same,</p> <p>23 that you're not aware for any</p> <p>24 communications that Mylan's valsartan API</p>	<p style="text-align: right;">Page 678</p> <p>1 Can a product be both -- can</p> <p>2 Mylan's valsartan API or finished dose be</p> <p>3 both high quality and adulterated at the</p> <p>4 same time?</p> <p>5 MR. TRISCHLER: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: Adulteration</p> <p>8 is not a definition that I define.</p> <p>9 I'm not a lawyer. I'm not a</p> <p>10 regulator.</p> <p>11 High quality is probably</p> <p>12 something that is more</p> <p>13 generalized.</p> <p>14 And so it's certainly</p> <p>15 possible that a product can be</p> <p>16 high quality one day and by the</p> <p>17 FDA's definition, adulterated the</p> <p>18 next.</p> <p>19 So that's as good as I can</p> <p>20 give it to you.</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. How about, can Mylan's</p> <p>23 valsartan API and finished dose be both</p> <p>24 high quality and not manufactured under</p>

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1 cGMP controls sufficient to assure the
2 quality of the product?
3 MR. TRISCHLER: Objection to
4 the form. Vague.
5 Objection. Incomplete
6 hypothetical.
7 Objection. Beyond the scope
8 because it has nothing to do with
9 anything.
10 BY MR. DAVIS:
11 Q. You can answer the question,
12 Mr. Glover.
13 A. Yeah. I mean, there's
14 really no answer to it. I mean, not
15 manufactured under GMP conditions is so
16 incredibly vague, that it's as varied as
17 the impression of the people that would
18 make that statement, whether it's
19 inspectors, regulators, auditors.
20 And so you can absolutely be
21 high quality and have someone have an
22 opinion about your GMP compliance status.
23 That happens every day for every company
24 across the world.

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1 Q. Well, not just someone
2 having an opinion in the case of
3 valsartan API manufactured at Unit 8.
4 Unit 8 received a warning letter after
5 two inspections, and it's still under
6 "official action indicated" status,
7 correct?
8 MR. TRISCHLER: Objection to
9 the form.
10 Asked and answered about 62
11 times over the course of Day 3 of
12 this deposition.
13 But if you want to answer
14 again whether there's -- whether
15 "official action indicated" is the
16 status of Unit 8 --
17 THE WITNESS: Right.
18 MR. TRISCHLER: -- please
19 let's do it again.
20 THE WITNESS: Unit 8 is
21 under OAI status at this point.
22 FDA's 483s and warning
23 letters reflect their opinion of
24 conditions they found in the

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1 facility.
2 It doesn't necessarily
3 reflect what we agree and
4 certainly doesn't mean that our
5 products aren't high quality.
6 BY MR. DAVIS:
7 Q. It reflects the FDA's
8 position of cGMP deviations at Unit 8,
9 correct?
10 MR. TRISCHLER: Objection
11 to -- objection to form.
12 Objection. Asked and
13 answered.
14 THE WITNESS: Yeah, again,
15 it reflects certain opinions of
16 certain people.
17 BY MR. DAVIS:
18 Q. It reflects the opinions of
19 the agency, correct?
20 MR. TRISCHLER: Objection.
21 THE WITNESS: People within
22 the agency. I mean, look, I don't
23 know how many times I have to tell
24 you. I don't necessarily agree

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1 with the FDA's, you know, position
2 on certain topics.
3 And so, yeah, if you're
4 asking me if FDA issued a warning
5 letter for Unit 8, yes, they did.
6 Are they under OAI status?
7 Yes, they are.
8 If you're asking me more
9 about their opinion, you should
10 call them.
11 BY MR. DAVIS:
12 Q. Well, right. And I'm trying
13 to get at -- those are agency actions,
14 correct, not actions of some individual
15 acting on their own directives within
16 the agency. Those are official FDA
17 agency actions that have been taken,
18 correct?
19 A. That's not necessarily true
20 though. I mean, they begin an end with
21 an individual's opinion. And so I'm not
22 going to spend an exhaustive amount of
23 time describing the operation within the
24 agency. It doesn't really matter.

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1 I can validate for you that
2 Unit 8 is -- has received a warning
3 letter and is under OAI status.
4 I can't tell you what FDA's
5 opinion is.
6 Q. Okay. But it's not, you
7 know, John Doe at the FDA who personally
8 decides that, you know, Mylan Unit 8 is
9 OAI, and that's his personal opinion.
10 When Mylan's Unit 8 is
11 listed as OAI, that's an official agency
12 action that's being taken, correct?
13 MR. TRISCHLER: Objection.
14 THE WITNESS: It is.
15 MR. TRISCHLER: Asked and
16 answered.
17 THE WITNESS: And it also
18 establishes that Unit 8 can
19 continue to distribute all of its
20 product in the United States.
21 So if FDA really had a major
22 concern, they wouldn't be allowing
23 the product to come through the
24 customs border.

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1 So I don't think it's fair
2 to equate warning letter or OAI
3 status with some type of, you
4 know, grand concern about the
5 quality of the products.
6 It's the process of
7 regulation. It's the way FDA
8 communicates opportunities to
9 enhance certain procedures.
10 BY MR. DAVIS:
11 Q. Well, didn't you just tell
12 me I'd have to go talk to someone at the
13 FDA to get their personal opinions on
14 this stuff? And now you're saying -- now
15 you're drawing conclusions about what is
16 in their minds, are you not?
17 A. I'm not. I'm stating facts.
18 I'm giving you the fact that FDA has not
19 placed an import ban on Unit 8.
20 Q. They have not yet, have
21 they?
22 A. Yet? Is that a question?
23 No, FDA has not issued an import ban.
24 Q. Okay. And that's yet,

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1 because Mylan is still, in the FDA's
2 designation, is OAI, meaning that Mylan's
3 Unit 8 has not resolved the agency's
4 objections to the GMP conditions there,
5 correct?
6 MR. TRISCHLER: Objection to
7 the form. Misstates facts.
8 Mischaracterizes evidence.
9 You can answer again.
10 THE WITNESS: Yeah, again, I
11 think from our position, we
12 believe we have satisfied the
13 FDA's concerns and we've provided
14 that information to them.
15 BY MR. DAVIS:
16 Q. Are you familiar with what,
17 if anything, Mylan conveys directly to
18 wholesalers or other direct purchasers of
19 Mylan's valsartan API and finished dose
20 regarding the contents and purity of
21 valsartan API or finished dose?
22 A. Do you mean as far as
23 official communication? No, I'm not
24 aware of what materials are provided.

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1 I'm not across that, no.
2 Q. Okay. Let's take an
3 example.
4 MR. DAVIS: I'm marking Tab
5 309 as Exhibit 76.
6 (Document marked for
7 identification as Exhibit
8 PL-Glover-76.)
9 THE WITNESS: Okay. I have
10 it.
11 BY MR. DAVIS:
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

<div data-bbox="235 92 878 1050">[REDACTED]</div>	<div data-bbox="878 92 1534 1050">[REDACTED]</div>
<div data-bbox="235 1050 878 1999">[REDACTED]</div>	<div data-bbox="878 1050 1534 1999">[REDACTED]</div>

[illegible]

1 it.
2 BY MR. DAVIS:

18 MR. DAVIS: I'm going to
19 mark Exhibit 312 -- sorry, Tab 312
20 as Exhibit 77.

21 (Document marked for
22 identification as Exhibit
23 PL-Glover-77.)

24 THE WITNESS: Okay. I have

<p>Page 699</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

15 MR. DAVIS: I'm going to
16 mark Tab 314 as Exhibit 79.
17 (Document marked for
18 identification as Exhibit
19 PL-Glover-79.)
20 THE WITNESS: I have it.
21 BY MR. DAVIS:

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[REDACTED]

MR. DAVIS: Okay. We've been going about an hour, Clem. Do you want to take a break?

MR. TRISCHLER: Whenever you want to, John.

MR. DAVIS: Okay. That's fine. Let's take a break. I've got a -- I'm going to transition to a new topic. We can go off the record.

THE VIDEOGRAPHER: Okay. The time is 10:45 a.m. Off record.

(Short break.)

THE VIDEOGRAPHER: The time is 11:02 a.m.. back on record.

BY MR. DAVIS:

Q. Okay. Mr. Glover, we've been talking about Topics 36, 37, 38, and 39 of the notice. I'm just going to share my screen one more time with Plaintiff Glover-2.

And I'll just go through

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[REDACTED]

each of them. For 36, Mylan's oral and written communications with its valsartan API customers including vertically integrated facilities or other downstream entities, regarding the quality, purity, or contamination issues related to Mylan API."

What documents have you reviewed that fall within that topic?

MR. TRISCHLER: Objection. Asked and answered.

THE WITNESS: Right, so, I mean, I predominately remember looking at e-mails.

So, you know, I know this topic has come up numerous times throughout preparation, but I don't have a lot of memorized content about what we were actually reviewing.

So -- but the e-mail is what I remember as one of the best examples of this type of communication.

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1 BY MR. DAVIS:
2 Q. Okay. What are you -- what
3 oral or written communications are you
4 aware of that fit within Topic 36?
5 MR. TRISCHLER: Same
6 objection. Asked and answered.
7 THE WITNESS: I don't have
8 them memorized. I just know I've
9 had many e-mails put in front of
10 me that tend to fall in this
11 category. So that's what I'm
12 aware of. I just don't have them
13 memorized.
14 BY MR. DAVIS:
15 Q. Okay. Well, your testimony
16 earlier was that it was a couple of
17 e-mails. Is it now many e-mails?
18 A. I'm sorry. It's more than
19 one, and less than, you know, 50. I
20 don't know. When you asked me the
21 question earlier, I think you -- I at
22 least understood you to be talking about
23 something maybe a little more narrow in
24 scope.

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1 Now that you showed me the
2 scope of this, with like five subparts or
3 four subparts, it's a group of e-mails.
4 I can't say exactly how big it is, but
5 that was the general topic, as this topic
6 kept coming up.
7 Q. And you can't tell me who
8 the e-mails were from or to?
9 A. No. I really don't have
10 like a memorized list of e-mails in my
11 head. I'm sure they will be familiar
12 when you pull them up. But I think it
13 was a variety of different customers,
14 people, internal people.
15 Most of the names are not
16 familiar to me, which is probably one of
17 the main reasons that I don't have them
18 memorized is they tend to be people from
19 the India facility.
20 Q. So these were internal
21 e-mails mostly?
22 A. A lot of them are, yes.
23 Q. Okay.
24 A. There are some external as

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1 well.
2 Q. For the external ones, do
3 you recall whether they were directed to
4 wholesalers, retailers, consumers, TPPs,
5 finished dose manufacturers?
6 A. No. I feel like it was
7 generally customers, you know, so people
8 that were purchasing the API.
9 Q. So finished dose
10 manufacturers, mostly?
11 A. That makes sense, yeah.
12 Q. Okay. Is the answer the
13 same for 37, which is -- the only
14 difference being it relates to Mylan's
15 finished dose?
16 A. Yes. Yeah. Same answer.
17 Q. Okay. Did you ask anyone at
18 Mylan to say, hey, what have we
19 communicated regarding our API or
20 finished dose to wholesalers, retailers,
21 consumers or TPPs?
22 A. I mean, when I looked for
23 documents or information to support this
24 discovery, I was really looking for

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1 mainly things that I could find on
2 valsartan and nitrosamines.
3 So I don't know that I
4 intentionally went out there and tried to
5 find communication or e-mails. I assumed
6 that others were sort of doing that
7 search.
8 Again, I wasn't in this
9 capacity back in 2018. And so there
10 wouldn't be anywhere near as much, if
11 any, of that type of communication that I
12 would have had personally.
13 Q. Have you ever --
14 A. So I wouldn't have been able
15 to find that.
16 Q. Sorry, I didn't mean to cut
17 you off there. You said that you relied
18 on other people?
19 A. Yes.
20 Q. Okay. Have you ever, in
21 your time at Mylan, been involved
22 directly with oral and written
23 communications with finished dose
24 facilities that are external to Mylan,

<p style="text-align: right;">Page 715</p> <p>1 wholesalers, retailers, consumers, or 2 TPPs? 3 A. It's extremely unusual. 4 Many, many years ago it's 5 possible that I would have gotten on the 6 phone with a customer to talk about an 7 ongoing investigation -- or I shouldn't 8 say a customer. I should say a supplier. 9 That was usually something 10 that -- if we had an ongoing 11 investigation from an incoming supply and 12 I wanted to get on the phone to talk to 13 them directly, on very, very rare 14 occasions, I would do that. That would 15 be verbal or oral. It's incredibly 16 unusual. I can't remember a time where I 17 would have written to a customer. 18 Q. Okay. And you said you -- 19 for 36 and 37, you didn't specifically go 20 ask anyone at Mylan to provide you with, 21 you know, what was communicated orally or 22 in written format for any of the entities 23 listed in Topics 36 or 37, correct? 24 A. That's correct.</p>	<p style="text-align: right;">Page 717</p> <p>1 what department you would go to? 2 A. Yeah, again, I don't really 3 know who handles the interface with the 4 customer. 5 I don't know the commercial 6 operations world that well to be able to 7 tell you. I really don't know. 8 Q. Okay. But you mentioned 9 commercial operations. Is that where you 10 think those people who would have this 11 information would be? 12 A. Yeah. I mean, the people 13 that worked -- I think we talked about, 14 you know, somebody like Joe Duda before. 15 And so he's -- you know, that's the type 16 of area that, you know, you would 17 probably begin to ask questions about to 18 find out who actually faces the customer. 19 I really don't know who those people are. 20 Q. And do you know whether -- 21 you might have said this already. 22 Do you know whether Joe Duda 23 is an employee of Mylan still or not? 24 A. I'm not sure. Yeah, I'm not</p>
<p style="text-align: right;">Page 716</p> <p>1 MR. TRISCHLER: Excuse me. 2 Sorry. 3 BY MR. DAVIS: 4 Q. And is it the same thing for 5 38 and 39? You did not in fact go ask 6 anyone for oral or written statements to 7 any of those listed people or entities 8 with regard to the contents or purity of 9 finished dose or API for valsartan? 10 A. Correct. 11 Q. Okay. Who, if you did -- if 12 you had gone and asked someone, who would 13 you have asked for that information? 14 MR. TRISCHLER: Object to 15 the form. 16 THE WITNESS: I really don't 17 know who handles that. I wouldn't 18 even know where to begin. I would 19 probably have asked counsel to, 20 you know, tell me who they were 21 already working with, is how I 22 would have started. 23 BY MR. DAVIS: 24 Q. Okay. You don't even know</p>	<p style="text-align: right;">Page 718</p> <p>1 sure. 2 Q. Did you -- were you 3 surprised to see that you were designated 4 on these topics? 5 MR. TRISCHLER: Objection to 6 form. 7 THE WITNESS: No, only 8 because it says valsartan and so I 9 assume that valsartan and 10 nitrosamines, that those documents 11 would be, you know, covered. 12 And we did cover many, or, 13 you know, several of those e-mail 14 communications. So that doesn't 15 seem -- 16 BY MR. DAVIS: 17 Q. Did you -- and I'm going to 18 ask you to limit your answer to this 19 question to yes or no. But did you ask 20 counsel in preparation for this what 21 these topics meant or were asking for? 22 MR. TRISCHLER: Objection. 23 I think you just asked him to 24 tell -- I think you just asked for</p>

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1 him to disclose a privileged
2 communication.
3 MR. DAVIS: No. I asked --
4 MR. TRISCHLER: You asked --
5 you asked him -- what -- you asked
6 what questions he asked of counsel
7 to help prepare him for this
8 deposition.
9 MR. DAVIS: Well, let me
10 ask --
11 MR. TRISCHLER: I believe
12 that's privileged.
13 MR. DAVIS: Let me ask it a
14 different way.
15 BY MR. DAVIS:
16 Q. Did you -- you said that
17 your interpretation of these was based on
18 valsartan and nitrosamines, correct?
19 That's what you just testified?
20 A. Correct.
21 Q. Okay. But nowhere in any of
22 these -- let's take 38 and 39 for
23 example.
24 Nowhere in Topics 38 or 39

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1 is contamination or nitrosamine
2 contamination mentioned at all, right?
3 MR. TRISCHLER: Objection to
4 form.
5 THE WITNESS: I see the word
6 "purity." And so I just assumed
7 that the word purity is also
8 inferring that this is valsartan
9 API and the situation related to
10 nitrosamine.
11 BY MR. DAVIS:
12 Q. And my follow-on question
13 is -- and again, yes or no, did you have
14 any conversations with counsel regarding
15 what these 36 through 39 actually meant?
16 Just yes or no.
17 A. We had a discussion about
18 each one of these items.
19 Q. Are you aware of any
20 presentations that were made to finished
21 dose manufacturers regarding the contents
22 or purity of Mylan's API for valsartan?
23 A. What do you mean by
24 presentation?

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1 Q. Sure. You know, you've
2 referred, I believe, to finished dose
3 manufacturers that are external as
4 customers, correct? Would you agree that
5 those are customers of Mylan for API?
6 A. Yes.

[REDACTED]

[REDACTED]

Page 723

[REDACTED]

Page 725

1 information than others. And so
2 you've shown me enough documents
3 in the past hour and a half that
4 I'm at least aware that they seem
5 to be somewhat interested in
6 getting some information about
7 the, you know, the supplier of the
8 products.
9 But I'm not very familiar
10 with that.
11 BY MR. DAVIS:
12 Q. Okay. And are you at least
13 familiar enough that wholesalers tend to
14 buy directly from the manufacturer?
15 A. Yeah, I am aware. Yeah, I'm
16 sorry. Yeah.
17 Q. And as we saw, for example,
18 that -- when that contractual
19 relationship for Mylan to supply its
20 product to a wholesaler is entered into,
21 that comes with some documents that are
22 signed, correct?
23 MR. TRISCHLER: Objection to
24 the form.

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[REDACTED]

9 Q. Okay. What about
10 wholesalers? What's your understanding
11 of how Mylan interacts with wholesalers
12 for generic pharmaceutical products?
13 MR. TRISCHLER: Objection to
14 form.
15 Objection. Beyond the
16 scope.
17 THE WITNESS: Yeah, I'm not
18 super familiar with the
19 relationship management side of
20 wholesalers.
21 I know there's a variety of
22 different, you know, dynamics that
23 are at play there.
24 Some wholesalers want more

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1 Objection. Beyond the
2 scope.
3 THE WITNESS: Yeah, I would
4 be completely assuming or
5 speculating that there is. But I
6 think you've shown me at least
7 one.
8 BY MR. DAVIS:
9 Q. And so in order to secure
10 that business from wholesalers -- because
11 they are customers of Mylan as well,
12 right? They purchase product from Mylan?
13 A. Yes.
14 Q. Okay. Are you familiar with
15 what Mylan conveyed to wholesalers
16 regarding the contents and purity of its
17 valsartan API or finished dose?
18 A. I am not, no.
19 Q. Okay. Who would I speak to
20 to get more information about that?
21 A. Again, I have no idea who
22 that would be.
23 Q. Okay. Are you familiar that
24 some retailers also source directly from

Page 727

1 manufacturers?

2 A. Yeah.

3 Q. Okay. And is your answer

4 the same for them, you're not familiar

5 with what was conveyed to them?

6 A. That's correct.

7 Q. Okay. And how about

8 consumers, did you -- I believe you said

9 that you had not looked at the patient

10 information leaflet that I showed you

11 which was Exhibit 70, correct?

12 A. I had not reviewed it. I

13 was familiar that they exist, though.

14 Q. Okay. And did you review

15 any communications that Mylan had with

16 consumers regarding the contents and

17 purity of Mylan's valsartan API or

18 finished dose?

19 A. I'm not sure.

20 Q. What about quality or

21 contamination issues of Mylan's API or

22 finished dose, 36 and 37, for consumers?

23 A. For consumers? I would have

24 reviewed the -- at minimum, I'm sure I

Page 728

1 saw the recall notice.

2 Q. Okay. Any -- can you recall

3 anything else?

4 A. I'm not sure.

5 Q. Would you agree that

6 consumers are, you know, the ultimate,

7 you know, beneficiary of receiving

8 quality pharmaceutical products? They're

9 the ones who ingest them, right?

10 MR. TRISCHLER: Objection to

11 form.

12 THE WITNESS: Yeah.

13 BY MR. DAVIS:

14 Q. Sorry. You can answer,

15 Mr. Glover.

16 A. I answered yes.

17 Q. Thank you. Do you recall --

18 I can't remember if this was Day 1 or Day

19 2 of the deposition. We were talking

20 about process validation for recovered

21 solvent processes.

22 Do you recall that

23 discussion?

24 A. Yeah.

Page 729

1 Q. Okay. And I believe you

2 told me that process validation documents

3 for those processes would sit at the

4 supplier; is that correct?

5 A. I think you have to be more

6 specific. Can you say that --

7 Q. Sure. I can even -- I can

8 even quote you back to you. You said the

9 process validation for recovery would

10 likely sit at the service provider

11 itself. And then for Unit 8, Lantech was

12 the name of the company that was the

13 service provider.

14 Do you recall telling me

15 that?

16 A. I'm sure we were -- sorry.

17 I'm sure we were speaking

18 about a very specific unit operation

19 validation.

20 So if, in fact, there was a

21 process validation that was performed

22 specific to the recovery itself with no

23 other context, then yes they would do it

24 at their site.

Page 730

1 Q. Okay. And you said that

2 those documents would live at the site?

3 A. I was speculating, but, yes,

4 I would assume that if they existed,

5 they'd live at the site.

6 MR. DAVIS: I'm marking Tab

7 305 as Exhibit 80.

8 (Document marked for

9 identification as Exhibit

10 PL-Glover-80.)

11 THE WITNESS: Okay.

12 BY MR. DAVIS:

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 Q. Okay. And he's e-mailing

Page 731

1 that to several individuals at Mylan,
2 correct?

3 A. Yep.

4 Q. Okay. The EDQM is what
5 again?

6 A. They're a European health
7 authority. I won't be able to tell you
8 specifically. I get them confused with
9 EMA all the time. But they're either an
10 outsource or contract group that does
11 inspections for EMA, or there's some
12 relationship between EMA and EDQM.

13 Q. Are they like a sub-agency
14 within EMA or --

15 A. That's how I've always
16 understood it. Well, I don't know that
17 they are actually a part of EMA. I think
18 the EMA just uses them to perform
19 inspections. But again, don't quote me.
20 I'm not exactly sure.

21 Q. Okay. Do you know --

22 A. Or they represent the health
23 authority. Yeah.

24 Q. Okay. Understood.

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1 MR. DAVIS: I'm going to
2 mark Tab 306 as Exhibit 81, which
3 is the attachment.

4 (Document marked for
5 identification as Exhibit
6 PL-Glover-81.)

7 THE WITNESS: Okay.

8 BY MR. DAVIS:

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
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8 [REDACTED]
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<div>Page 735</div> <div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

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THE VIDEOGRAPHER: The time is 11:41 a.m. Back on record.

MR. DAVIS: Michelle, can you read back the last question and answer. I lost my place.

(Whereupon, the court reporter read back the requested portion of testimony.)

BY MR. DAVIS:

Q. You said you assumed that it was acceptable based on the specification, correct?

A. That was the established acceptance criteria, right.

Q. That's -- you're referring to the specification there?

A. Yeah.

(Zoom freeze.)

(Whereupon, a discussion was held off the record.)

MS. HILTON: Let's go off the record. I'm going to see what's going on for John.

THE VIDEOGRAPHER: Okay. The time is 11:37 a.m. Off record.

(Short break.)

[REDACTED]

14 process. I'm not sure.

15 Q. Okay.

16 MR. DAVIS: I'm marking Tab
17 307 as Exhibit 82.

18 (Document marked for
19 identification as Exhibit
20 PL-Glover-82.)

21 THE WITNESS: Okay.

22 BY MR. DAVIS:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<div>Page 747</div> <div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

Page 751

[REDACTED]

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1 subject of which appears to be in
2 Japanese.
3 Do you see that?
4 A. Yes.
5 Q. Okay. I'm going to direct
6 you to -- you'll see in the bottom right
7 corner there's a Bates number, and then
8 there's an underscore, and then there's
9 three numbers after the underscore. I'm
10 going to direct you to 007.
11 A. Okay.
12 Q. Do you see that the full
13 e-mail on that page is from Sandra
14 Blondell to Dr. Gomas and Jyothi
15 Abbineni, among others?
16 A. Yes.
17 Q. Do you know who is an Sandra
18 Blondell is?
19 A. She's the head of quality
20 for Australia, New Zealand. I think she
21 has Japan as well.
22 Q. Okay. And so she reports up
23 to you as the global head of quality,
24 correct?

10 MR. DAVIS: I'm going to
11 mark Tab 301 as Exhibit 83.
12 (Document marked for
13 identification as Exhibit
14 PL-Glover-83.)
15 MR. TRISCHLER: John, can
16 you repeat that, please? I'm
17 sorry.
18 MR. DAVIS: Tab 301, which
19 is Exhibit 83 that I've just
20 marked.
21 THE WITNESS: Okay.
22 BY MR. DAVIS:
23 Q. You'll see that this is a
24 relatively lengthy e-mail chain, the

Page 754

1 A. She reports to Dr. Gomas, I
2 believe or Patrick -- well, it's
3 Dr. Gomas, I think.
4 Q. Who then reports to you,
5 correct?
6 A. Correct.
7 Q. Okay. So Ms. Blondell is
8 within your chain of command, so to
9 speak?
10 A. Yes.
11 Q. Okay. Do you see where she
12 says -- and this is November 21st, 2018.
13 She says, "For example we saw" -- "For
14 example, in valsartan we saw that NDEA
15 was BDL for the Japan batches due to
16 additional purification."
17 Do you see that?
18 A. I do.
19 Q. What is she saying there?
20 MR. TRISCHLER: Objection.
21 Excuse me.
22 Objection. Beyond the
23 scope.
24 Objection to form.

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1 THE WITNESS: I'm sorry. I
2 don't understand the question.
3 Are you asking me what BDL
4 stands for, or are you asking me
5 something else.
6 BY MR. DAVIS:
7 Q. Well, sure. Let's start
8 there. What does BDL mean?
9 A. I think it means below
10 detection limit.
11 Q. Okay. Was it true that VSJ
12 batches of valsartan for Japan were below
13 detection limits for NDEA?
14 MR. TRISCHLER: Objection to
15 form.
16 Objection. Beyond the
17 scope.
18 THE WITNESS: Yeah, I don't
19 have the Japanese data memorized,
20 and I don't know what context this
21 e-mail was written within.
22 BY MR. DAVIS:
23 [REDACTED]
24 [REDACTED]

[REDACTED]

19 MR. TRISCHLER: Hey, John.
20 MR. DAVIS: Yeah.
21 MR. TRISCHLER: Can we take
22 a lunch break -- I neglected to
23 raise this earlier. Can we take a
24 lunch break around 12:15? I've

Page 757

1 got a court conference on another
2 case at 12:30, and I just want to
3 take five or ten minutes to get
4 ready for that.
5 MR. DAVIS: Yeah, we can --
6 do you want to break right now?
7 MR. TRISCHLER: No, we can
8 go for another 10, 15 minutes. I
9 just wanted to alert you that I
10 would like to stop at 12:15.
11 MR. DAVIS: Sure. That
12 sounds good. I'll just finish
13 this topic up, and then we can
14 stop.
15 MR. TRISCHLER: That's why I
16 was telling you, so that you could
17 maybe plan a little bit. But I
18 appreciate it.
19 BY MR. DAVIS:
20 Q. Going to Page 005 -- well,
21 really 4 and 5 of this Exhibit 83.
22 You'll see an e-mail from -- and reply
23 from Mr. Abbineni?
24 A. Yeah.

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[REDACTED]

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1 THE VIDEOGRAPHER: Okay.
 2 The time is 12:22 p.m. Off
 3 record.
 4 (Excused.)
 5 (Deposition adjourned at
 6 approximately 12:22 p.m., EST.)
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1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition
 4 over carefully and make any necessary
 5 corrections. You should state the reason
 6 in the appropriate space on the errata
 7 sheet for any corrections that are made.
 8 After doing so, please sign
 9 the errata sheet and date it.
 10 You are signing same subject
 11 to the changes you have noted on the
 12 errata sheet, which will be attached to
 13 your deposition.
 14 It is imperative that you
 15 return the original errata sheet to the
 16 deposing attorney within thirty (30) days
 17 of receipt of the deposition transcript
 18 by you. If you fail to do so, the
 19 deposition transcript may be deemed to be
 20 accurate and may be used in court.
 21
 22
 23
 24

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1
 2 CERTIFICATE
 3
 4
 5 I HEREBY CERTIFY that the
 6 witness was duly sworn by me and that the
 7 deposition is a true record of the
 8 testimony given by the witness.
 9
 10 It was requested before
 11 completion of the deposition that the
 12 witness, RICHARD DEREK GLOVER, have the
 13 opportunity to read and sign the
 14 deposition transcript.
 15
 16 MICHELLE L. GRAY,
 17 A Registered Professional
 18 Reporter, Certified Shorthand
 19 Reporter, Certified Realtime
 20 Reporter and Notary Public
 21 Dated: April 20, 2021
 22
 23 (The foregoing certification
 24 of this transcript does not apply to any
 reproduction of the same by any means,
 unless under the direct control and/or
 supervision of the certifying reporter.)

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 4 PAGE LINE CHANGE
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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 626 - 768, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

RICHARD DEREK GLOVER

Subscribed and sworn
to before me this

_____ day of _____, 20____.

My commission expires: _____

Notary Public

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Exhibit 100

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 - - -

4 IN RE: VALSARTAN, LOSARTAN, : MDL No. 2875
5 AND IRBESARTAN PRODUCTS : HON ROBERT B. KUGLER
6 LIABILITY LITIGATION : CIVIL NO. 19-2875 (RBK/JS)

7 _____

8 THIS DOCUMENT APPLIES TO ALL :
9 CASES :

10 - - -

 APRIL 15, 2021

11 VOLUME II

12 - - -

13 - CONFIDENTIAL INFORMATION -

14 SUBJECT TO PROTECTIVE ORDER

15 Continued Remote Videotaped
16 Deposition, taken via Zoom, of DANIEL
17 BARRETO, commencing at 8:33 a.m., on the
18 above date, before Amanda Maslynsky-Miller,
19 Certified Realtime Reporter and Notary
20 Public in and for the Commonwealth of
21 Pennsylvania.

22 - - -

23 - - -

24 GOLKOW LITIGATION SERVICES

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 I N D E X
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Testimony of: DANIEL BARRETO

By Mr. Stanoch	429, 769
By Ms. Lockard	685

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2	(It is hereby stipulated and		
3	agreed by and among counsel that		
4	sealing, filing and certification		
5	are waived; and that all		
6	objections, except as to the form		
7	of the question, will be reserved		
8	until the time of trial.)		
9	- - -		
10	VIDEO TECHNICIAN: We are		
11	now on the record. My name is		
12	Kristalyn Duran, a videographer		
13	for Golkow Litigation Services.		
14	Today's date is April 15th, 2021,		
15	and the time is 8:33 a.m.		
16	This is a video deposition		
17	of Daniel Barreto, Volume 2.		
18	Counsel, you may proceed.		
19	- - -		
20	DANIEL BARRETO, after having		
21	been previously duly sworn, was		
22	further examined and testified as		
23	follows:		
24	- - -		

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1 EXAMINATION
2 - - -
3 BY MR. STANOCH:
4 Q. Thank you. Good morning,
5 Mr. Barreto, welcome back.
6 A. Good morning, counsel.
7 Q. You understand you're still
8 under oath from yesterday?
9 A. I do.
10 Q. Great. And just a yes or
11 no, did you talk to your counsel, between
12 the end of yesterday's deposition session
13 and today, about your testimony so far?
14 A. Yes.
15 Q. Did you talk to anyone else
16 besides in-house or outside counsel for
17 Teva about your testimony so far?
18 A. No.
19 Q. Did you review any documents
20 since we ended last night and this
21 morning?
22 A. Yes.
23 Q. How many documents did you
24 review?

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1 A. I browsed through, probably,
2 ten, fifteen documents just to refresh my
3 memory.
4 Q. Were those documents you had
5 already coming into yesterday's
6 deposition?
7 A. No, sir.
8 Q. These were new documents
9 that were just made available to you last
10 night?
11 A. Yes, sir.
12 Q. And they were made available
13 to you by your counsel?
14 A. Yes, sir.
15 Q. About how much time did you
16 spend looking at those documents?
17 A. Ten to fifteen minutes.
18 MS. LOCKARD: And just for
19 the record, some of that includes
20 what we discussed producing to you
21 this morning.
22 MR. STANOCH: Thank you, Ms.
23 Lockard.
24 BY MR. STANOCH:

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1 Q. Mr. Barreto, yesterday we
2 talked a little bit about risk
3 assessments and test results that Teva
4 generated concerning the ZHP and Mylan
5 valsartan API.
6 Do you recall that
7 generally?
8 A. Yes, sir.
9 Q. I'm just going to put in
10 front of you what's been previously
11 marked as Teva-16.
12 A. Let me go to -- are you --
13 counsel, are you going to share that so
14 that I can upload it?
15 Q. I'm happy to share my
16 screen, if that -- if you thought that
17 was smoother yesterday.
18 A. It worked. But I think
19 looking at the document just gives me the
20 ability to sort of look at some sections
21 that allow me to better, you know, make
22 myself more acquainted with it.
23 Q. That's fine. So what I'll
24 do, sir --

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1 MR. STANOCH: Go ahead,
2 Victoria.
3 MS. LOCKARD: I'm sorry. We
4 don't have the link anymore on the
5 chat.
6 So, Amanda, are you able to
7 add that?
8 COURT REPORTER: Certainly.
9 THE WITNESS: Thank you,
10 counsel.
11 BY MR. STANOCH:
12 Q. What I'll do, Mr. Barreto,
13 is I'll share my screen initially to make
14 sure you're looking at the same thing and
15 then you can peruse the copy you have,
16 okay?
17 A. That sounds fine.
18 Q. This document was previously
19 marked in another deposition as Teva-16.
20 It's a July 18, 2019, e-mail
21 from Mr. Sawyer to you and others, and
22 it's copying a number of final Teva
23 reports, and they're listed here; the
24 risk assessment of Teva for the ZHP

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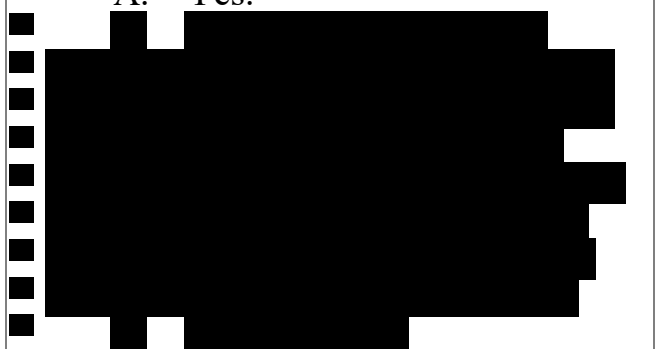
1 valsartan API, the risk assessment for
2 the Mylan valsartan API, and then Teva's
3 analytical drug substance and drug
4 product testing results for the --
5 A. Yes.
6 Q. Do you see that?
7 A. Yes, sir.
8 Q. And these are -- these
9 appear just to be final, signed copies of
10 the reports. We looked at maybe other
11 drafts or iterations yesterday.
12 You're familiar with these
13 reports, correct?
14 A. Yes. Yes, I am.
15 Q. For example, I'm looking at
16 the first one, which is Teva's risk
17 assessment concerning the ZHP valsartan
18 API, right?
19 A. Yes, sir.
20 Q. And this appears to be the
21 final version of that?
22 A. Yes, sir.
23 Q. And you reviewed this before
24 it was finalized and signed off on by

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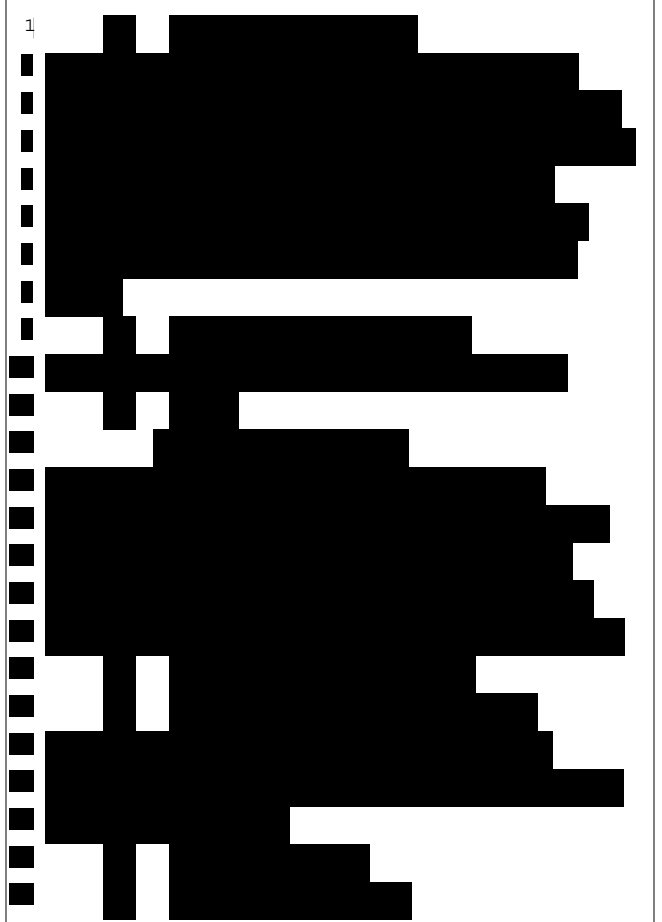
1 Teva?
2 A. I did.
3 Q. And a similar question here
4 for the risk assessment for the Mylan
5 valsartan API, sir.
6 A. That is correct.
7 Q. This appears to be the final
8 version of Teva's risk assessment for
9 that API, correct?
10 A. That is correct.
11 Q. And you reviewed this prior
12 to its sign-off and approval?
13 A. I did.
14 Q. And finally is the Teva
15 valsartan analytical drug substance and
16 drug product testing results sourced from
17 ZHP.
18 Do you see that?
19 A. Yes, I do.
20 Q. Again, this appears to be
21 the final version of that?
22 A. That is correct.
23 Q. Right. And you were
24 familiar with this document when it was

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1 prepared and finalized?
2 A. I am.
3 Q. In fact, I think you
4 approved this; that's your signature,
5 correct, for July 18th --
6 A. That is correct. That is my
7 signature.
8 Q. July 18th, 2019, right?
9 A. That is correct.
10 Q. And we looked at a slightly
11 different version of this one yesterday
12 regarding the results of Teva's testing
13 of valsartan API from ZHP.
14 Do you recall that?
15 A. Yes.



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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 Q. And are you aware of a
11 similar document that was prepared like
12 this for the Mylan valsartan API that
13 Teva was sourcing?
14 A. I believe we may have put
15 something together, yes.
16 Q. And I know -- I know that
17 there were test -- we talked yesterday
18 that Teva did eventually conduct testing
19 of the Mylan valsartan API, right?
20 A. Certainly we did, yes.
21 Q. And I believe we discussed
22 how those results, in some form or
23 fashion, were shared, ultimately, with
24 the FDA as well, right?

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1 A. Yes, they were.
2 Q. Right. And whatever those
3 results are, they are as reflected in the
4 communication to the FDA; is that fair?
5 A. That is correct.
6 Q. And just sitting here today,
7 do you have a memory, one way or the
8 other, of whether, you know, a sort of
9 formal document, it was sort of like this
10 layout, was prepared by Teva for the
11 Mylan valsartan API as well?
12 A. I believe we did something
13 similar to that.
14 Q. And we talked about this
15 yesterday, that, ultimately, Teva's own
16 testing revealed there was NDEA in Mylan
17 valsartan API batches, correct?
18 A. That is correct.
19 Q. And I believe we also
20 discussed that Teva's own testing
21 eventually revealed that NDMA was also in
22 at least some of the Mylan valsartan API
23 batches, correct?
24 A. I believe so.

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1 Q. And prior to that testing,
2 Mylan had told Teva that the formation of
3 NDMA was not possible via the Mylan
4 valsartan API manufacturing process,
5 right?
6 A. And they documented this
7 through an assessment that we requested
8 them to perform. We reviewed that
9 assessment from them.
10 And at the time when the
11 assessment was reviewed, based on the
12 information that we had with respect to
13 how this impurity could be formed, we
14 concluded that that assessment was
15 reasonable and usable.
16 Q. But, ultimately, Teva's own
17 testing revealed that there was some NDMA
18 detected in Mylan's valsartan API,
19 correct?
20 A. And that testing, yes,
21 confirmed that. So, therefore, the
22 initial assessment that was done needed
23 additional support through the process of
24 testing, which was done.

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1 Q. Can you tell me why all of
2 the valsartan API batches that Teva
3 sourced from Mylan did not contain NDMA
4 under the FDA interim limit of 0.3 PPM?
5 A. Can you repeat the question,
6 please?
7 Q. Sure.
8 Can you tell me why all of
9 the valsartan API batches that Teva
10 sourced from Mylan were not under the FDA
11 interim limit for NDMA of 0.3 PPM?
12 A. I'm trying to remember at
13 this point.
14 I know we had the issue with
15 the cross-contamination coming from the
16 solvents for the NDEA issue. So if I
17 recall, I think it was also an issue of
18 contamination versus an issue of the
19 manufacturing process itself.
20 Q. Can you tell me why all of
21 the valsartan API batches that Teva
22 sourced from Mylan were not under the
23 interim FDA limit of 0.08 PPM for NDEA?
24 A. My understanding, based on

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1 the investigation, was that there was a
2 cross-contamination issue coming from the
3 o-xylene solvent.
4 Q. And with respect to the
5 Mylan valsartan API, as part of the Teva
6 risk assessment that's in this collection
7 of documents here, that issue concerning
8 cross-contamination from the o-xylene
9 solvent was identified as one of the
10 reasons why Teva concluded that it
11 would -- it would, until further notice,
12 not source valsartan API from Mylan?
13 A. What is your question,
14 counsel? My apologies.
15 Q. The issue that you noted
16 with the o-xylene contamination for the
17 Mylan API, right --
18 A. Right.
19 Q. -- are you with me?
20 That issue, Teva ultimately
21 determined, contributed to an
22 unacceptable risk which led to Teva,
23 until further notice, not sourcing
24 valsartan API from Mylan?

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1 And I can refer you to the
2 risk assessment.
3 A. Yes. I think it is, based
4 on our assessment, we needed to
5 understand the extent to which the use of
6 the solvent across a number of batches
7 would have, you know -- we were looking
8 at impact.
9 So we were trying to
10 understand, what is the extent of this
11 cross-contamination? So this is
12 something that needed further
13 investigation from us and we needed to
14 make sure that we had that information.
15 So, for us, it was important
16 to have more information as to how many
17 batches were actually implicated.
18 Q. Ultimately, in Teva's risk
19 assessment that we're looking at here,
20 Teva concluded that it discontinued
21 sourcing valsartan and valsartan
22 intermediates from Mylan for all markets
23 due to an unacceptable level of risk,
24 correct?

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1 A. That is correct.
2 Q. So it wasn't just a certain
3 batch or a certain lot of API from Mylan,
4 because of the risk of
5 cross-contamination that Teva
6 investigated that was happening at Mylan,
7 it discontinued, at this time, at least,
8 of this report, sourcing any valsartan
9 API because of the unacceptable level of
10 risk?
11 A. So from our perspective, as
12 I indicated to you, when you have an
13 issue like this where you find
14 cross-contamination, in this case, from
15 solvents, it's not that easy to sort of,
16 let's say, conclude that this is
17 isolated, so X number of batches.
18 So the fence, as we call it
19 in this industry, is something you still
20 have to establish. So we did not have
21 the fence, and we needed to get more
22 information.
23 Q. As part of Teva's
24 investigation into the contamination

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1 issue with the Mylan valsartan API, did
2 Teva have any communications with the
3 company that was providing the solvent to
4 Mylan?
5 A. Not to my knowledge.
6 Q. A moment ago you mentioned
7 that it's not too easy to determine, when
8 you have an issue like this,
9 cross-contamination from the solvent with
10 Mylan.
11 Is that because there's no
12 assurance that all of the drugs do not
13 contain the nitrosamine contaminant?
14 A. No. It's because you want
15 to understand, from a technical
16 perspective, you know, where are the
17 solvents used. So o-xylene may be used
18 in one process but not in others.
19 So we really wanted to
20 understand how we could assess and get a
21 better picture as to, first, when did
22 this cross-contamination happen, under
23 what circumstances and whether or not
24 this, let's say, cross-contaminated

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1 o-xylene was used, when -- so there's
2 more information that you want to get in
3 a responsible fashion.
4 Because you know, first,
5 that you have to get this information for
6 yourself, you have to be comfortable
7 it's a very comprehensive investigation.
8 And you also know that in the process of
9 explaining, if you -- if you, let's say,
10 do not recall certain batches, you still
11 have to provide an explanation to the
12 regulators as to how you came to that
13 conclusion.
14 Q. This is one of the reasons
15 why good documentation is important at an
16 API manufacturer, right?
17 A. Good documentation is
18 necessary for every single one of the
19 activities that -- so this is a good
20 reason.
21 But it's also a good reason
22 for every single activity that is
23 assessed.
24 Q. And that includes, for

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1 example, the manufacture of API, yes?
2 A. That includes, yes, the
3 manufacture of the API, that is included,
4 yes.
5 Q. That includes Teva's own
6 testing of incoming API from a vendor?
7 A. That is correct.
8 Q. And that includes an API
9 vendor's own sourcing of solvents or
10 other intermediates from another third
11 party?
12 A. I would expect that that
13 would be the case.
14 Q. And this is why it's
15 important for manufacturers to audit
16 their suppliers to make sure they have
17 all the necessary documentation?
18 A. That is correct. And that's
19 why we have that process for auditing.
20 And we ascertain, to the best of our
21 abilities, that any data that is
22 generated, any documentation, is -- is
23 trustworthy.
24 Q. Does Teva know what Mylan's

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1 process was for auditing its own
2 suppliers?
3 A. In general, I'm sure we do
4 know, because we do know our own process.
5 But this is not an area where we do
6 not -- we will necessarily delve into,
7 because that's -- that is mostly their
8 responsibility.
9 Q. And the -- turning to the
10 risk assessment that Teva performed
11 concerning the valsartan API from ZHP
12 now.
13 Again, it was Teva's
14 conclusion -- and feel free to look at
15 the document -- that it was an
16 unacceptable risk because of the
17 potential for the nitrosamine impurities
18 that could arise during the manufacturing
19 process, right?
20 A. That is correct.
21 Q. And we talked about this a
22 little bit yesterday.
23 Part of that was the use of
24 certain solvents at certain stages of the

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1 manufacturing process, the process known
2 as the zinc chloride process?
3 A. The use of solvents is a
4 common practice as part of this process,
5 yes.
6 Q. I mean, I was focusing
7 specifically on almost the root cause
8 with the nitrosamine contamination for
9 the valsartan API from ZHP.
10 Do you remember talking
11 about that a little bit yesterday?
12 A. I do -- I do remember
13 talking about that. And about the root
14 cause, yes, sir.
15 Q. Right. And I'm happy to
16 flip through the risk assessment, but my
17 understanding was the root cause had to
18 do with the use of solvents, you know,
19 reacting with another -- another chemical
20 at a certain stage of ZHP's manufacturing
21 process?
22 A. That would not be correct --
23 Q. Why don't -- tell me. Tell
24 me, then, what --

<p>Page 449</p> <p>1 A. Yes. So from the assessment 2 that we did of the investigation -- 3 solvents are commonly used now. In this 4 case, DMF has a certain -- traces that 5 are -- or degradants that are generated, 6 one of them being the DEA. 7 So what happens is that 8 these small traces which are, I would 9 say, secondary to the principal 10 manufacturing process, these are the 11 traces that, when they are combined with 12 nitrous acid, those are the ones 13 triggering the formation of the -- of the 14 impurity. 15 So when you look at the 16 manufacturing process at ZHP, it's not 17 the use of the solvents themselves that 18 trigger the formation of the impurities. 19 That's my point. 20 Q. Right. The solvents in and 21 of themselves were not what Teva 22 identified as a root cause issue; it was 23 the reaction of the traces of the solvent 24 with another chemical substance?</p> <p>Page 450</p>	<p>Page 451</p> <p>1 a separate quenching, you're able to 2 pretty much separate and create a barrier 3 between the product and the aqueous layer 4 where the -- you know, these impurities 5 could be present. 6 And that would allow them to 7 ensure that the product would be free 8 from -- let's say, relatively free, 9 because I don't want to say that -- I 10 don't want to use the term -- I'm using 11 the term "free" freely here. No pun 12 intended. 13 So -- but the theory is 14 in -- and their testing shows that when 15 they do that separate quenching, you're 16 able to segregate the opportunity for 17 these NDMA's -- NDMA to be in the product. 18 Q. And I take your 19 qualification with freely, because when 20 Teva and ZHP were talking, in the fall of 21 2018, I've seen a number of documents 22 where ZHP says, you know, the nitrosamine 23 cannot form anymore when you're doing the 24 quenching separately, but then I think</p> <p>Page 452</p> <p>1 some of Teva's audit work suggested that 2 there still might be some amount of NDMA 3 being generated. 4 Do you recall that? 5 A. I do. But I think, again, 6 it's -- the important thing here is these 7 manufacturing processes are very complex, 8 industrial. So even the separation of 9 layers, it's not a perfect science. 10 So that's why I think 11 that -- the concept is that there was a 12 solution that would create a product that 13 would be within specifications. And I 14 think that's what they meant to say. 15 Q. Right. In my -- one of my 16 points and something, you know, people 17 might ask is, ZHP never told Teva about 18 the nitrosamine contamination until late 19 June 2018, right? 20 A. And from our understanding, 21 we didn't have any reasons to believe 22 that -- based on our audit and based on 23 the testing they had performed and based 24 on the testing we had performed of their</p>
<p>1 A. Not traces of the solvent. 2 But traces of degradants that are formed 3 within that process. And these are very 4 small traces. 5 So diethylamine is -- let's 6 call it a by-product of, let's say, that 7 reaction that takes place. But it's 8 not -- it's not a solvent itself. It's 9 just a by-product that comes into -- it's 10 formed during that manufacturing process 11 at trace levels. 12 Q. Absent the DMF that was 13 being used, was it Teva's assessment that 14 the nitrosamine impurities could form? 15 A. Besides the DMF, no. 16 Q. Right. And I think we 17 talked about it a little yesterday, ZHP 18 undertook to do something called the zinc 19 chloride optimized process, correct? 20 A. That is correct. And what 21 they -- what they did is that they did 22 further investigation and they confirmed 23 that when you do the quenching at the 24 next step, and you execute what is called</p>	

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1 product, we had no reason to believe that
2 there were nitrosamines in the product.
3 Q. And a couple of months later
4 Teva audited ZHP in September of 2018,
5 right?
6 A. Yes, I believe so.
7 Q. And ZHP told Teva, hey, we
8 have an optimized process now, NDMA can't
9 be formed anymore, right?
10 A. I have to look at the
11 details. What -- I think what they said
12 is they had an optimized process where
13 they could separate the NDMA from the
14 product.
15 Q. Right. And then when Teva
16 took a look at that in the context of its
17 fall 2018 audit, it still found some
18 traces of NDMA in the valsartan API,
19 right?
20 A. That may have been the case.
21 And it goes back to what I
22 was saying, it's not a perfect process,
23 so I -- in my experience, it's very
24 difficult for anybody in this industry to

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1 make a claim that something is going to
2 be totally free from traces of
3 nitrosamines.
4 Q. Would that be the same for
5 any chemical that might be in a product,
6 that might be hard to --
7 A. Theoretically --
8 theoretically speaking, based on what we
9 know, there's always -- theoretically
10 speaking, there's always an opportunity,
11 whether it's coming from, I don't know,
12 different sources, water, theoretically
13 speaking, I don't think it can be ruled
14 out.
15 And I think it would be the
16 smart thing not to assume that you don't
17 want to look into those things.
18 Q. Right. That's what Teva was
19 doing in the fall of 2018, right? That
20 even though ZHP was saying, hey, we have
21 an optimized process now, NDMA can't
22 form, Teva was doing the smart thing at
23 that time and verifying that to see if
24 that was, in fact, the case; is that

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1 fair?
2 A. I think that the knowledge
3 that we all gained gave us the
4 opportunity to take a more proactive
5 approach.
6 And even still in September
7 '18, we're still looking into whether or
8 not we still needed to learn more things.
9 So I think that what we did was the right
10 thing, because, obviously, this is, as we
11 said, an evolving process. So we kept
12 learning as we went.
13 Q. In the fall of 2018, Teva
14 just didn't take ZHP's word for it that
15 NDMA is completely removed from the new
16 optimized process, it sought to verify
17 that itself, correct?
18 A. Absolutely. And we felt
19 that it was important to do that because,
20 again, we wanted to make sure that
21 whatever we needed to do to bring this
22 problem to -- also, with the
23 understanding that the regulatory
24 authorities, DDQM, FDA, were also

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1 operating toward the same end.
2 So we were looking not only
3 at our own perspective on how to deal
4 with this issue, but also taking into
5 consideration what the health authorities
6 were doing.
7 Q. You recall some testimony
8 yesterday about whether ZHP ever informed
9 Teva, or specifically legacy Actavis at
10 the time, of ZHP's process change from
11 the TEA process to the zinc chloride
12 process?
13 A. I do recall that, yes.
14 Q. Right. And we looked at an
15 e-mail you wrote in July 2018 in which
16 you stated that ZHP never informed Teva,
17 but you subsequently came to believe that
18 might have -- you might have been
19 mistaken when you drafted that e-mail,
20 right?
21 A. At the moment when they -- I
22 drafted that e-mail, I did not have the
23 information. And, you know, you get
24 input from different people, and

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1 that's -- that was the input I received.
2 So we stood corrected.
3 In fact, you know,
4 there's -- there's significant
5 information, including the Teva, you
6 know, amendment to the ANDA in 2013,
7 where the reason for that amendment is
8 that there was a zinc chloride process
9 for the API, and we submitted it at
10 CBE 30.
11 Q. Right. You did mention
12 that. And I am going to put that in
13 front of you to make sure I have the
14 right one that you're thinking of.
15 One moment, sir.
16 A. Yes, sir. Thank you. What
17 exhibit number will that be?
18 MR. STANOCH: I have not
19 done it yet.
20 THE WITNESS: Okay. Thanks.
21 My apologies.
22 BY MR. STANOCH:
23 Q. Sir, this is a document
24 that's been previously marked as Teva

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1 Exhibit-2.
2 A. Yes.
3 Q. It's a September 9, 2014,
4 CBE letter from Watson, which is, I
5 guess, eventually Actavis, which
6 eventually was part of Teva?
7 A. That is correct.
8 Q. And was this one of the
9 submissions that you were referring to a
10 moment ago?
11 A. That is correct.
12 Q. And there is -- there is
13 another one for -- a different ANDA for a
14 slightly different valsartan product
15 that --
16 A. Yes, that is correct.
17 See, I think it's the
18 amlodipine, yeah, and then this one is --
19 because these are combination products.
20 Q. Right. And I'll just put
21 that, just so you have it, I'll put
22 that -- this was previously marked as
23 Teva Exhibit-3.
24 A. Thank you.

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1 Q. Do you see that one, too,
2 that's the other one you were thinking
3 of?
4 A. Let me look at it, sir.
5 Q. Sure.
6 A. I was looking at the first
7 one.
8 That would be 003, correct?
9 Q. And do you recall --
10 A. Yes.
11 Q. These are the two
12 submissions you were thinking about in
13 terms of whether or not ZHP had told
14 Teva, or legacy Teva -- or a legacy
15 entity that Teva acquired about the
16 process change from the TEA process to
17 the zinc chloride process, right?
18 A. That is correct, counsel.
19 Q. And, again, can you refresh
20 my memory of when you think you saw these
21 two letters?
22 A. I saw these during my
23 initial review of the documentation that
24 I received.

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1 These are -- all preceded my
2 time, so this is part of the package of
3 documentation that I have been able to
4 see.
5 Q. Got it.
6 You first saw these letters
7 in preparation for this deposition, not
8 when you were actually at Teva, is what
9 you're saying?
10 A. That -- what I'm trying to
11 say is that the discussion about whether
12 or not Teva had been informed, this is
13 something that I -- came about during
14 the -- further during the process at the
15 company.
16 But the actual, you know,
17 review of these documents, as part of
18 this process, yes, is during my review
19 process for this discussion.
20 Q. Thank you.
21 And I think the statements
22 are almost the same, so I don't -- I'll
23 just look at one of the letters, but --
24 I'll look at Exhibit-3. But I'm happy to

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1 look at either of them.
2 A. That's fine. I'm on
3 Exhibit-3. That will be fine.
4 Q. Great. And the letter notes
5 to the FDA about minor to moderate
6 modifications were made to ZHP's DMF,
7 right?
8 A. That is correct.
9 Q. And then it goes on to list
10 or summarize what some of the -- what the
11 minor to moderate changes are, right?
12 A. Correct.

[REDACTED]

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[REDACTED]

Page 463

[REDACTED]

Page 464

[REDACTED]

Page 465

■ [REDACTED]

7 Q. Right. Sitting here today,
8 you don't know what testing might have
9 been done by ZHP to determine whether or
10 not DMF and MTBE had, in fact, been
11 completely removed?

12 A. Right. But what I do know
13 is that in the process, based on my
14 experience, of determining the
15 specifications that you would establish
16 for your finished product, those
17 specifications are based on the
18 expectation that you have, based on your
19 studies and your experiments and your
20 process controls, that these
21 specifications have to be challenged
22 because you expect, for instance, for
23 residual solvents, methanol, ethenol,
24 they expect that there's a possibility

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1 that there could be some residual levels
2 of those.

3 So, again, I'm only speaking
4 from my experience. I may be
5 speculating. But based on my experience
6 in this industry, all I'm saying is it
7 would be good to see the extent to which
8 these solvents are checked as an
9 in-process -- if an in-process check is
10 performed for ensuring that the previous
11 step, whatever that is, removed those
12 impurities in the way they were supposed
13 to -- sorry, those solvents the way they
14 were supposed to be.

15 Q. You don't know at all what
16 Watson, Actavis, however you want to
17 label the entity, did itself to see
18 whether there was an in-process check
19 concerning DMF and MTBE, right?

20 A. I do know that we pursued
21 the -- all the testing that was necessary
22 to ensure that the product fulfilled the
23 specifications.

24 Q. Right. But the

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1 specification we're looking at does not
2 have any specification test for DMF and
3 MTBE, right?

4 A. That is correct. But
5 that's -- those specifications were
6 neither set by the regulatory
7 authorities. And they also do an
8 assessment of the manufacturing process.

9 Q. Well, the regulatory
10 authority is not doing any testing
11 itself; you're not aware of that with
12 respect to ZHP's valsartan API, are you?

13 A. But the regulatory
14 authorities do have an important process,
15 both DDQM, FDA, and also the USB, in the
16 design of the analytical test method.
17 That -- those specifications are founded
18 on what they understand are the
19 conditions under which the products are
20 manufactured.

21 Q. You understand that DMF
22 changes of minor or moderate does not
23 require prior FDA approval for it to be
24 instituted, correct?

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1 A. Could you repeat the
2 question?

3 Q. You understand that a minor
4 to moderate modification to a DMF does
5 not require prior approval from the FDA
6 before it's instituted, correct?

7 A. That is correct.

8 Q. And you were talking about
9 the stage in which the solvent was used.

10 Does the usage of a solvent
11 towards the end of the manufacturing
12 process change your testimony regarding
13 in-process checks for solvents such as
14 DMF and MTBE?

15 A. Not necessarily. As I
16 indicated to you, the -- the end of the
17 process could be defined still --
18 there -- there may be two or three steps
19 or four steps before, and that still may
20 be considered part of the end of the
21 process, because, let's say, it's that
22 stage of the manufacturing process where,
23 you know, now you have a better defined
24 molecule that you want to call, let's

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1 say, the crude active ingredient for
2 instance, and you still don't have a
3 finished product.
4 Q. Well, here ZHP had a
5 four-step process, and they're saying at
6 Step 4, right, that's the last step, the
7 solvents were being added, right?
8 A. It's not as simple as that.
9 And, again, I would have to
10 refresh myself with what do they mean by
11 one step. One step could actually have a
12 number of activities associated with it.
13 So it's not as simple as
14 just saying a step means one action. It
15 could mean a number of actions that take
16 place within that step.
17 Q. You don't know what, if
18 anything, Watson and Actavis did at the
19 time to ensure or verify that DMF and
20 MTBE were being removed completely during
21 the valsartan manufacturing process,
22 correct?
23 MS. LOCKARD: Objection.
24 Asked and answered.

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1 THE WITNESS: What I do --
2 what I do know is that there were
3 a number of assessments done and
4 there were a lot of test
5 activities that were performed and
6 risk assessments that were
7 performed.
8 So those risk assessments
9 and those testing activities are
10 actually designed to directly and
11 indirectly confirm that the
12 expectation that we have for the
13 product are met.
14 BY MR. STANOCH:
15 Q. Let's look at one of those
16 risk assessments, okay.
17 MR. STANOCH: I'm going to
18 mark the next Teva exhibit, which
19 should be --
20 THE WITNESS: Yes, sir.
21 MR. STANOCH: I believe
22 we're up to 162.
23 - - -
24 (Whereupon, Exhibit

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1 Teva-162,
2 TEVA-MDL2875-00950663-0706, Risk
3 Assessment for the Use of
4 Valsartan, was marked for
5 identification.)
6 - - -
7 THE WITNESS: Allow me a
8 second.
9 Yes, sir.
10 BY MR. STANOCH:
11 Q. So this appears to be a risk
12 assessment for the use of valsartan
13 sourced from a new dedicated workshop.
14 And it's Bates ending 950663.
15 Do you see this?
16 A. Yes, sir.
[REDACTED]

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[REDACTED]

Page 473

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 Q. Can you tell me or identify
10 for me any risk assessment performed by
11 Actavis, or another legacy entity that
12 was acquired by Teva, that solely looked
13 at the valsartan API manufacturing
14 process for the zinc chloride procedure?
15 A. I'm sure -- I'm sure there
16 is that document. I don't have it in
17 front of me right now.
18 Q. Well, have you seen that
19 document?
20 A. I may have seen that
21 document.
22 Q. But you can't tell me at all
23 what it looks like, what it says, when
24 it's dated? Can you tell me anything
about it?

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1 A. I believe -- I believe I've
2 seen a risk assessment document. But I
3 am trying to remember now what it would
4 look like. I believe I have seen it,
5 yes.
6 Q. And who drafted it?
7 A. That must have been, if I
8 recall well, it was a cross-functional
9 activity started with the R&D
10 organization.
11 Q. And does that document spell
12 out what testing, if any, that Actavis
13 did for DMF and MTBE in the valsartan API
14 that ZHP was making under the zinc
15 chloride process?
16 A. I do not think that that was
17 included. I don't remember. But I do
18 not think that was included.
19 Q. And let's go look through
20 this assessment a little bit, sir.
21 If you flip to the --
22 A. Yes.
23 Q. -- the first page, it's Page
24 2 of 6, Bates ending 664.

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1 A. Okay. I'm here, okay. So 2
2 of 6, and which paragraph are you looking
3 at?
4 Q. I'm just looking at the risk
5 identification section.
6 Do you see that, sir?
7 A. Yes, I see it.
8 Q. And this -- it talks about
9 the CEP being updated and the main
10 changes.
11 And you see the bullets
12 there for the changes being discussed?
13 A. I do.
14 Q. And these are all changes to
15 the valsartan API that was being made by
16 ZHP and purchased by Actavis, right?
17 A. Correct.
18 Q. And these are the same, if
19 not -- these are -- strike that.

20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. That's right.
12 Actavis's own risk
13 assessment on whether or not DMF and MTBE
14 were being purged consistently was coming
15 from what ZHP told Actavis, right?
16 A. That is correct.
17 Q. You're not aware of Actavis
18 doing anything itself to ensure that DMF
19 and MTBE were, in fact, being purged
20 consistently, are you?
21 A. I -- specifically about
22 testing, no. But, obviously, we did
23 review the process validation activities
24 associated with that change. That was

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1 provided to Actavis at the time.
2 So the data that was
3 generated -- as I told you before, the
4 data that was generated gave Actavis the
5 confidence that the process validation
6 activities removed these two solvents.
7 Q. All of that data that
8 Actavis relied on came from ZHP, correct?
9 A. That is correct. And
10 that's -- that's normal. You would not
11 necessarily double check everything that
12 API or another contractor gives you.
13 You look at the data, you
14 look at the -- let's say the protocol
15 that was developed, the approach that was
16 established. You look at the raw data
17 that was generated. You would look at
18 the finish -- and then you would make
19 your decision.
20 Q. This sentence -- this
21 paragraph also continues, In addition,
22 the batch size will be scaled up within
23 tenfold (twofold) at the third dedicated
24 workshop.

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1 Do you see that?
2 A. Yeah, I do.
3 Q. What does that mean?
4 A. That means that the size of
5 the batch would be increased.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 Q. Did Actavis ask ZHP to see

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1 the new residual solvent testing results
2 for DMF and MTBE at the commercial scale?
3 A. I don't have that
4 information.
5 But I do know that Actavis
6 received information from CHP that would
7 allow Actavis to come to a conclusion as
8 to whether or not, you know, the
9 information that was given was sufficient
10 for them not to pursue any further
11 information.
12 Q. Whatever information ZHP
13 gave to Actavis concerned ZHP's testing
14 at the lab scale, correct?
15 A. I would not necessarily say
16 that. I'm sure that -- as part of the
17 evaluation process, we would have looked
18 at the process validation activities,
19 because that's important.
20 And per my understanding,
21 this process was actually already used
22 for other markets. So it is my
23 understanding that ZHP will have
24 generated more information on this

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1 process.
2 Q. You're not aware of any test
3 results that ZHP provided to Actavis at
4 this time concerning commercial scale
5 valsartan API, are you?
6 A. I'm -- specifically not.
7 But I am aware of the fact that Actavis
8 reviewed the process validation
9 activities, which would include that type
10 of testing.
11 Q. But you don't know whether
12 or not that testing occurred or if it was
13 shared with Actavis, do you?
14 MS. LOCKARD: Object to
15 form. Asked and answered.
16 THE WITNESS: As I indicated
17 to you, that information was
18 evaluated by Actavis.
19 BY MR. STANOCH:
20 Q. Where is it evaluated in
21 this risk assessment, sir?
22 A. It's part -- as part of the
23 process -- it's not necessarily in the
24 risk assessment. The risk assessment is

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1 a summary.
2 But as I indicated to you,
3 the change was notified and Actavis took
4 the necessary actions to request the
5 information that would help Actavis to
6 make a decision that this was a minor
7 change.
8 In order to -- in order to
9 make that decision, you have to have the
10 data. You cannot say it's minor without
11 the data. That's my point.
12 Q. First of all, you don't
13 know, one way or the other, whether
14 Actavis requested this or if ZHP gave it
15 to them, number one, right?
16 A. That is part of the process.
17 In order to make a submission to the FDA,
18 the -- Actavis has to obtain this
19 information. This information is
20 requested. This is -- it's part of the
21 process.
22 Q. And all that information
23 that Actavis, in turn, used to respond to
24 the FDA was from ZHP, right?

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1 A. It is from ZHP, correct.
2 Q. Right. And looking at --
3 looking at both the letters that Actavis
4 sent to the FDA about the change and this
5 Actavis risk assessment about the change,
6 there's no mention of any independent
7 testing that Actavis did itself to
8 confirm that DMF and MTBE is completely
9 removed during the process, correct?
10 A. Correct. And neither is any
11 follow-up from the FDA, in terms of the
12 submission, which is also part of the
13 review process, where FDA is requesting
14 Actavis to pursue any additional work.
15 So the submission that we
16 made to FDA was deemed to be acceptable.
17 Q. Well, it's on Actavis to be
18 accurate when it submits things to the
19 FDA, right?
20 A. That is correct.
21 But it's also the
22 responsibility, and we see this whenever
23 there is what seems to be a deficiency in
24 terms of information, it is routine for

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1 the FDA to return the submission back to
2 us and to request additional information.
3 This is routine.
4 Q. Well, this was a CBE, sir;
5 that's going to take effect no matter
6 what. The FDA doesn't have to do
7 anything, correct?
8 A. That's not correct. FDA may
9 change a CBE to a prior approval
10 supplement. So it may do or may not do
11 nothing.
12 But FDA does have the
13 opportunity and the ability to review.
14 And they do review.
15 So the fact that FDA did not
16 take an action is an indication to us
17 that FDA understood that the information
18 we had provided was sufficient.
19 Q. You don't know what the FDA
20 thought when they looked at the Actavis
21 submissions, do you?
22 MS. LOCKARD: Objection.
23 Objection. Argumentative.
24 THE WITNESS: But I do know

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1 that if FDA does not submit any
2 objection, that means that FDA's
3 review is acceptable, to us.
4 BY MR. STANOCH:
5 Q. So you're telling me unless
6 the FDA affirmatively says there's a
7 problem, that everything is okay and
8 there is no problem; is that what you're
9 telling me under oath?
10 A. That is not -- that is not
11 correct.
12 Q. I agree. That isn't
13 correct, right.
14 Just because the FDA doesn't
15 take an action doesn't mean there's
16 something wrong, correct?
17 A. Let me explain.
18 Q. Answer my question, then you
19 can explain.
20 MS. LOCKARD: Hold on.
21 MR. STANOCH: He can answer
22 my question and then explain, Ms.
23 Lockard.
24 MS. LOCKARD: I'm going to

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1 object to this argumentative
2 nature. This is just not
3 appropriate. You can make your
4 points without arguing with him,
5 please.
6 MR. STANOCH: I disagree
7 it's arguing. He can answer the
8 question and then explain his
9 answer.
10 Ms. Miller, would you mind
11 reading it back?
12 - - -
13 (Whereupon, the court
14 reporter read the following part
15 of the record:
16 "Question: I agree. That
17 isn't correct, right.
18 "Just because the FDA
19 doesn't take an action doesn't
20 mean there's something wrong,
21 correct?")
22 - - -
23 THE WITNESS: The answer
24 that I'm giving to you, counsel,

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1 is that we perform our own
2 self-regulated action to perform a
3 risk assessment, to look at the
4 data, to evaluate the data, and to
5 determine the extent to which we
6 need to do more or less with
7 respect to a submission like this
8 one.
9 We reviewed the data from
10 ZHP. We came to the conclusion
11 that this was a minor to moderate
12 change. We submitted this
13 document to the FDA, and we did,
14 on our side, what we felt and what
15 we understood was necessary to
16 make a proper submission.
17 And what I'm saying is that
18 FDA has two options. One is to
19 respond saying, we disagree with
20 your assessment, we would like to
21 have more information. Or, they
22 may just not say anything about it
23 because they find that the work
24 that we did was acceptable.

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1 BY MR. STANOCH:
2 Q. Did Actavis's submissions to
3 the FDA indicate that the information
4 being provided was derived from ZHP and
5 not from Actavis itself?
6 A. And I'm saying that we have
7 a combination of information that comes
8 from Actavis and ZHP to make the
9 submission. It's not just that. So --
10 Q. I'm going to keep asking,
11 sir, and your counsel can object. It's a
12 simple question.
13 Did Actavis's submission to
14 the FDA indicate that the information
15 provided was derived from ZHP and not
16 from Actavis?
17 MS. LOCKARD: Objection.
18 Asked and answered.
19 MR. STANOCH: You can
20 answer.
21 THE WITNESS: The answer --
22 the answer that we have is that in
23 the process of doing this
24 evaluation, we obtained

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1 information from ZHP that we found
2 to be acceptable, reliable and
3 trustworthy.
4 We analyzed that
5 information, we validated and
6 verified that information. Once
7 we go through that process, we're
8 comfortable to, basically, take
9 ownership for the fact that that
10 information is correct and it's
11 proper to be submitted to the FDA.
12 BY MR. STANOCH:
13 Q. So the answer is no, that
14 you do not see where, in the submission
15 to the FDA, Actavis indicated that the
16 information provided was derived from ZHP
17 and not from testing being done by
18 Actavis?
19 MS. LOCKARD: Objection.
20 Asked and answered.
21 THE WITNESS: The answer is
22 that we submitted information to
23 the FDA that we felt -- that we
24 took ownership for it, whether it

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1 came from ZHP or from other
2 sources.
3 BY MR. STANOCH:
4 Q. Show me in the submissions
5 to the FDA by Actavis where Actavis says,
6 this information about the complete
7 removal of DMF and MTBE was from our
8 testing, not ZHP's.
9 A. Counsel, I find that to be
10 irrelevant. I'm sorry.
11 But the responsibility to
12 determine, that comes from the API
13 supplier, they did their job, and our
14 responsibility was to review and
15 validate. And we did.
16 MR. STANOCH: Ms. Lockard, I
17 don't want to have to, for
18 something like this, on day two --
19 I'll just get Special Master
20 Vanaskie on the phone. Because if
21 it's a simple question of where
22 something is in a letter or not,
23 and if he can't answer that, I
24 think that's inappropriate.

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1 And now he's claiming my
2 questions are not relevant. So
3 I'd like you to direct your client
4 to answer the questions.
5 MS. LOCKARD: Let's just
6 take a break for a moment, okay.
7 I don't -- I'm happy to get
8 Vanaskie on the phone, that
9 doesn't scare me one bit.
10 But I think we can probably
11 get around this without bothering
12 Judge Vanaskie.
13 So if I understand your
14 question, you're just simply
15 asking him, does the document
16 specifically state that Actavis
17 told FDA that the testing was done
18 by ZHP and not Actavis?
19 Are you just asking what the
20 document says?
21 MR. STANOCH: Yes.
22 First of all, I'm not trying
23 to threaten or scare you, number
24 one. I'm just trying to move this

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1 along for everyone.
2 Number two, yes, that's what
3 I've asked four different ways.
4 If you'd like a break to talk to
5 your witness, that would be great.
6 MS. LOCKARD: Yeah. We've
7 been going about an hour anyway.
8 Let's just take a break, and we'll
9 come back.
10 MR. STANOCH: Okay. Sounds
11 good.
12 THE WITNESS: Thank you,
13 counsel.
14 MR. STANOCH: Thank you.
15 VIDEO TECHNICIAN: The time
16 is now 9:34 a.m. We are going off
17 the record.
18 - - -
19 (Whereupon, a brief recess
20 was taken.)
21 - - -
22 VIDEO TECHNICIAN: The time
23 is now 9:47 a.m. Back on the
24 record.

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1 BY MR. STANOCH:
2 Q. Mr. Barreto, did Actavis
3 inform the FDA, in its CBE submissions,
4 Teva Exhibits-2 and 3, that the
5 information it was relying on concerning
6 the removal of DMF and MTBE came from ZHP
7 or itself?
8 A. So, counsel, the document is
9 clear. It speaks for itself. It shows
10 that that information is not included.
11 Q. Thank you.
12 Turning back to the Actavis
13 risk assessment that we had been looking
14 at, sir.
15 A. Yes, sir.
16 Q. If you could turn to the
17 page ending --
18 A. Exhibit -- which exhibit,
19 please?
20 Q. I think this was --
21 A. 2 or 3?
22 Q. This is the -- this is the
23 newest one, sir, is it -- I think it's --
24 is it 161?

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1 A. Okay. Yes. Yes, sir.
2 Q. And if you can flip to the
3 page Bates ending 0690.
4 A. My -- okay. Counsel, can
5 you clarify what document we're looking
6 at? Because this is a string of e-mails.
7 Q. Okay. Give me one moment,
8 sir. I probably have the wrong number.
9 A. No problem.
10 Q. I'm looking at this
11 document, sir.
12 A. Just allow me to go back to
13 Zoom.
14 Oh, yes, sir.
15 Q. And you can look on the
16 screen, that might be more expedient, but
17 it's your choice.
18 I was turning to this page
19 specifically.
20 A. Yes.
21 Q. And this appears -- this is
22 a part of the information that's attached
23 to the Actavis risk assessment concerning
24 the ZHP process change for the valsartan

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1 API, right?
2 A. Yes, sir.
3 Q. And this is a change request
4 form from ZHP, yes?
5 A. That is correct.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 Q. Are you aware of anything

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1 Actavis did to independently verify for
2 itself, such as by testing, whether DMF
3 and MTBE were being purged consistently
4 as minimal from the zinc chloride process
5 at ZHP?
6 A. No. As far as I know, no
7 testing was done. Because, more than
8 likely, this was deemed not to be
9 necessary at the time.
10 MS. LOCKARD: Right. And
11 objection. Asked and answered.
12 BY MR. STANOCH:
13 Q. You don't know, one way or
14 the other, though, why no testing by
15 Actavis itself was done at the time, do
16 you?
17 A. Specifically, no.
18 Well, based on -- based on
19 the information that was reviewed, I can
20 understand and see why there was no need
21 for the testing to be done.
22 Q. For example --
23 A. Based on --
24 Q. I'm sorry. Go ahead.

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1 A. No, no. I mean, based on my
2 experience, counsel.
3 Q. For example, there's five
4 Actavis employees listed on this -- as
5 writing, reviewing and approving this
6 report, right?
7 Do you see that on the first
8 page?
9 A. Yes.
10 Q. Right. In preparation for
11 today's deposition, you never talked to
12 any of these folks, right?
13 A. No. I have not talked to
14 any one of them, no.
15 Q. And in preparation for
16 today's deposition, did you talk to
17 anyone who was at Actavis at the time of
18 this report who said whether or not and
19 why Actavis did or did not do its own
20 testing for DMF and MTBE in the valsartan
21 API zinc chloride process from ZHP?
22 A. No, I have not.
23 Q. And if we turn, then, to
24 another page here, sir.

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1 This is another -- it's a
2 change notification form from ZHP, which
3 is part of the backup information to the
4 Actavis risk assessment, right?
5 A. Yes.
6 Q. And among other things, this
7 change notification mentions that there's
8 a third dedicated workshop being applied
9 for valsartan commercial production,
10 right?
11 A. Yes.
12 Q. And it also mentions, This
13 copy of workshop and the scaling up has
14 not changed the manufacturing process.
15 The change does not adversely affect the
16 reproducibility of the process and the
17 specification of the final substance
18 remains the same.
19 Did I read that correctly?
20 A. You did.
21 Q. Are you aware of any
22 independent testing or review by Actavis
23 to confirm that the scaling up did not
24 change the manufacturing process for the

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1 valsartan that ZHP was now going to start
2 making using the zinc chloride process?
3 A. That would have been the
4 testing that was performed in accordance
5 with the USB requirements. So there was
6 extensive testing that was done.
7 That testing was included in
8 the process verification work that
9 Actavis did on the impact of the API on
10 the manufacturing process of the finished
11 product.
12 So the testing that was
13 conducted was in accordance with what was
14 established at the time.
15 Q. Where in this risk
16 assessment does it mention the testing
17 that Actavis did to ensure that the
18 scale-up of the manufacturing process did
19 not adversely affect the product or the
20 final substance?
21 A. I'm sorry, can you repeat
22 the question?
23 Q. Yes, sir.
24 Where in this risk

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1 assessment does it say that Actavis
2 confirmed for itself that the scale-up
3 did not change the manufacturing process,
4 reproducibility of the process, or
5 specification of the final substance via
6 the zinc chloride process at ZHP?
7 A. Well, you were speaking
8 about the scale-up.
9 And whether they were scaled
10 up or not, all the testing that was done
11 on the scale-up process was confirmed to
12 indicate that the product was meeting our
13 specifications.
14 Q. So there's no testing about
15 the scale-up process specifically in
16 connection with this risk assessment;
17 you're saying that it would have just
18 been the specification testing that
19 Actavis would be doing on incoming
20 batches after the scale-up occurred?
21 A. The scaled-up process is now
22 the manufacturing process, therefore,
23 that's what's going to be challenged.
24 And it was.

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1 Q. Was there any reference to
2 any independent testing or review by
3 Actavis in its risk assessment report
4 about whether it independently verified
5 whether the scale-up of the process did
6 not adversely affect reproducibility or
7 the specification of the final substance?
8 A. It may not have explicitly
9 stated that in that way. But the
10 approach of the process was to look at
11 this new manufacturing process as the
12 process that we were going to challenge.
13 And we did.
14 MR. STANOCH: One moment,
15 sir, I'm just going to pull up
16 another exhibit.
17 BY MR. STANOCH:
18 Q. In terms of -- sticking with
19 the same page we were looking at where
20 ZHP said the change does not adversely
21 affect the reproducibility of the
22 process, what's your understanding of
23 "reproducibility" in this context?
24 A. So can you be a little more

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1 specific? Because I want to be able to
2 answer your question.
3 Q. Sure.
4 I'm looking at the change
5 notification from ZHP.
6 A. Yep.
7 Q. And it says, This copy of
8 workshop and the scaling up has not
9 changed the manufacturing process.
10 A. Yes.
11 Q. The change does not
12 adversely affect the reproducibility of
13 the process.
14 A. Right.
15 Q. And I'm asking your
16 understanding of what reproducibility
17 of --
18 A. Yeah.
19 Q. -- the process means in that
20 context.
21 A. Understood.
22 So any process that is
23 implemented on a commercial basis goes
24 through certain stages of, you know, like

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1 what you said, you know, laboratory and
2 then scaled up at different levels until
3 it reaches the process validation stage.
4 So the process validation
5 process is intended to confirm that that
6 manufacturing process operates on a
7 consistent basis. So it's a way to
8 demonstrate now that you are confirming
9 the process itself, not -- you are
10 challenging the product, but you're also
11 challenging the process.
12 So reproducibility means
13 that so long as the process is operated
14 from one batch to the next in accordance
15 with that -- those settings and
16 conditions that were implemented, you
17 should be able to have a product that
18 will meet the specifications.
19 Q. I see. Thank you.
20 And is reproducibility a
21 goal of good manufacturing practices?
22 A. Absolutely, yes.
23 Q. And that's true for Teva's
24 own manufacturing and GMP compliance as

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1 well as the manufacturing and GMP
2 compliance of its vendors; is that fair?
3 A. That is true for every API
4 that is manufactured and every finished
5 product that is manufactured, yes.
6 Absence of process validation would
7 render that product unacceptable.
8 Q. Failure to ensure
9 reproducibility as well would suggest the
10 product is not compliant with GMP; is
11 that fair?
12 A. Not necessarily. I think
13 there are instances where certain things
14 happen that show that a batch, here and
15 there, is not necessarily reproducible,
16 but then those instances have to be
17 investigated. So it's not a straight
18 yes-or-no answer.
19 Q. It's a continuum, you're
20 saying?
21 A. That is correct.
22 Q. Right. And that -- whether
23 or not a given instance may be a one-off
24 or a systemic reproducibility issue is

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1 something you would expect a manufacturer
2 to investigate to ensure consistency with
3 GMP?
4 A. That is correct.
5 Counsel, can you just allow
6 me to put the phone on mute, I'll stay
7 on, just to clear my throat.
8 Q. Take a moment, sir.
9 A. Thank you, counsel.
10 Q. Not a problem.
11 You mentioned a number of
12 times today and yesterday test
13 specifications.
14 Is there a test
15 specification certificate of analysis
16 that, say, the Malta facility would use
17 to test incoming API?
18 A. So every -- every incoming
19 API that is purchased by a facility
20 brings with it a certificate of analysis.
21 And that certificate of
22 analysis will detail all the
23 specifications and test results that were
24 obtained and whether or not those tests

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1 passed.
2 Obviously, a non-passing
3 test, I would not expect it in a
4 certificate of analysis, because that
5 product should not have made it to the
6 customer, in general.
7 MR. STANOCH: I'm going to
8 mark the next exhibit, sir. This
9 is Teva-163.
10 - - -
11 (Whereupon, Exhibit
12 Teva-163, TEVA-MDL2875-00000875,
13 Test Specification and Certificate
14 of Analysis, was marked for
15 identification.)
16 - - -
17 THE WITNESS: Allow me to
18 get there.
19 BY MR. STANOCH:
20 Q. Sure. Tell me when it's on
21 your screen.
22 MR. STANOCH: In the
23 meantime, I'll note for the record
24 it's Bates ending 0875.

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1 THE WITNESS: Yes, I am
2 looking at it.
3 BY MR. STANOCH:
4 Q. This appears to be Arrow
5 Pharm, Malta, test specification and
6 certificate of analysis for valsartan.
7 Do you see that?
8 A. Yes.
9 Q. And this one is prepared,
10 checked and approved and is dated
11 September 5th, 2012?
12 A. Yes.
13 Q. This would relate to -- and
14 it says manufacturer of the valsartan is
15 Zhejiang Huahai, right?
16 A. Correct.

Page 507

[REDACTED]

Page 508

[REDACTED]

Page 509

[REDACTED]

Page 511

1 Q. And this one, again, is
2 about valsartan API coming from ZHP,
3 right?
4 A. Yes.
5 Q. And this one looks like it's
6 prepared, checked and approved July 4th,
7 2014?
8 A. I'm going to -- I'm looking
9 at that in a second.
10 Q. Sure.
11 A. Allow me.
12 That is correct.
13 Q. And these would be the tests
14 that Actavis in the Malta facility was
15 doing on the incoming valsartan API from
16 ZHP as of July 4th, 2014, right?
17 A. That is correct, sir.
18 Q. And, again, there's a number
19 of tests and methods and specifications
20 on the ensuing pages, yes?
21 A. Correct.
[REDACTED]

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1 MR. STANOCH: I'm going to
2 mark another exhibit, sir.
3 THE WITNESS: Yes.
4 MR. STANOCH: One moment.
5 This is Teva-164. Just tell
6 me when you have it in front of
7 you.
8 In the meantime, I'll state
9 for the record it's Bates ending
10 20116.
11 - - -
12 (Whereupon, Exhibit
13 Teva-164, TEVA-MDL2875-00020116,
14 Test Specification and
15 Certification of Analysis, was
16 marked for identification.)
17 - - -
18 THE WITNESS: Yes, sir.
19 BY MR. STANOCH:
20 Q. And this appears to be a
21 very similar test specifications and
22 certificate of analysis for Arrow, the
23 Malta facility, yes?
24 A. Yes.

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[REDACTED]

21 MS. LOCKARD: Object to the
22 form. Inconsistent with the
23 documents and the evidence.
24 MR. STANOCH: You can refer

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1 to other documents.
2 THE WITNESS: I assume that
3 would be correct.
4 BY MR. STANOCH:
5 Q. And I'll put another
6 exhibit, sir, that might be even more
7 clear for you in a moment, right now,
8 okay.
9 A. Yes. Because it's not that
10 explicit in the document.
11 Q. We looked at, earlier, the
12 CBE letters, right, and they were -- they
13 were submitted to the FDA.
14 Do you have them in front of
15 you?
16 A. I have to locate them, sir.
17 Q. Okay. Just so we're on the
18 same page.
19 MS. LOCKARD: I believe
20 those were Exhibit-2 and 3.
21 THE WITNESS: Yeah, I'm
22 looking at Exhibit-2. That would
23 be September 2014.
24 BY MR. STANOCH:

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1 Q. Got it. And the other one
2 is January 2015.
3 A. I have to look at it.
4 Q. To your knowledge, the
5 Actavis Malta facility, did it start
6 using valsartan API from ZHP made under
7 the zinc chloride process before it
8 submitted the CBE letters or only after
9 the letters were submitted and the time
10 to object by the FDA expired?
11 A. So from a regulatory
12 perspective, you cannot ship a product
13 that has not been approved by the FDA.
14 So, a current submission.
15 So you can use the new
16 material to engage in process validation
17 activities and to generate all the
18 information that is necessary. You can
19 even generate inventory, if that's what
20 you find to be necessary.
21 So that material, can it be
22 used? Yes, internally. Yes. Can it be
23 distributed? No.
24 Q. Understood.

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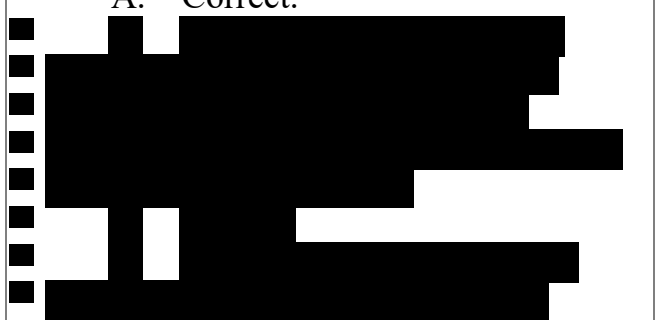
1 MR. STANOCH: I'm going to
2 mark another document, sir.
3 Teva-165.
4 THE WITNESS: Let me go
5 there.
6 MR. STANOCH: For the
7 record, I'll state it's Bates
8 ending 15517.
9 - - -
10 (Whereupon, Exhibit
11 Teva-165, TEVA-MDL2875-00015517,
12 Test Specification and Certificate
13 of Analysis, was marked for
14 identification.)
15 - - -
16 BY MR. STANOCH:
17 Q. And, sir, this appears to be
18 another Malta facility test specification
19 and certificate of analysis?
20 A. Yes.



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10 Q. So it's fair to say at this
11 point Actavis could have, and likely was
12 selling finished-dose valsartan to the
13 United States that contained ZHP
14 valsartan API made under the zinc
15 chloride process?
16 A. Correct.



Page 517

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. Whether or not it was
23 required by the regulators, it's correct
24 that Actavis was not testing for DMF and

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1 MTBE when it received valsartan API from
2 ZHP, correct?
3 A. That is correct.
4 Now, it said here that this
5 is a canceled document. I don't know if
6 that document is still applicable. So I
7 don't know if that's the document we
8 should be looking at.
9 Q. Well, are you aware that the
10 Malta facility was in the process of
11 transferring its production of
12 finished-dose valsartan to the Dupnitsa,
13 Bulgaria, facility?
14 Do you recall that?
15 A. I believe so.
16 Q. And, essentially, what it
17 was, was that Dupnitsa was going to start
18 receiving the valsartan API and making
19 the finished-dose valsartan for the U.S.
20 market instead of Malta; is that right?
21 A. That would have been the
22 case.
23 Q. Right. And in order to do
24 that, Dupnitsa would have to use the same

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1 methods that the Malta facility was using
2 to make the finished-dose valsartan,
3 right?
4 A. That is correct.
5 Q. Right. And, generally
6 speaking, there has to be a method
7 transfer, I believe it's called, correct?
8 A. It is a -- that is correct,
9 it's called method transfer.
10 Q. And that's to ensure that
11 the new facility will be doing the same
12 things as the facility previous?
13 A. That is correct.
14 Q. So there is --
15 MR. STANOCH: I'm going to
16 mark the next exhibit, sir.
17 THE WITNESS: Yes.
18 MR. STANOCH: This will --
19 give me one moment. This is
20 Teva-166.
21 - - -
22 (Whereupon, Exhibit
23 Teva-166,
24 TEVA-MDL2875-00242568-2678, GAP

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1 Analysis, Addition of Dupnitsa as
2 an Alternative Manufacturing Site
3 for Valsartan Tablets, was marked
4 for identification.)
5 - - -
6 MR. STANOCH: I'll state for
7 the record it's Bates ending
8 242568.
9 THE WITNESS: Okay.
10 BY MR. STANOCH:
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 Q. And do you recall when all

Page 521

1 of this -- all of this was being prepared
2 at Teva, the transfer?
3 A. I'm sorry? Say that again.
4 Q. Do you recall -- do you
5 recall when this transfer was supposed to
6 take place?
7 A. I don't remember exactly,
8 no.
9 Q. And I'll just say, there are
10 a number of documents about the
11 preparation for this from late 2017
12 through the first half of 2018.
13 Does that time period sound
14 about right to you?
15 A. Yes.
16 Q. And do you know whether --
17 if you recall, do you know whether the
18 method was transferred from Malta to
19 Dupnitsa?
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 523

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 Q. And if you scroll to -- one
7 moment while I get the page for you, sir.
8 A. Oh, yes.
9 MS. LOCKARD: I'm sorry,
10 what are we doing?
11 MR. STANOCH: I'm looking
12 for the page to direct the
13 witness, counsel. My apologies.
14 MS. LOCKARD: No worries.
15 We're still on 166?
16 MR. STANOCH: Yes, we are.
17 BY MR. STANOCH:
18 Q. Mr. Barreto, if you flip to
19 the page that's Bates number ending
20 242580.
21 A. What would be the heading,
22 counsel?
23 Q. It's going to be the
24 Parameter Number 11, residual solvents GC

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1 on the left.
2 A. Okay. Let me look for it.
3 Q. And I can -- I will share my
4 screen so you can see what I'm looking
5 at, and then you can find it.
6 A. I actually found it.
7 Q. Okay. You're quicker than I
8 am, sir.
9 A. Thank you.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q. Again, GC, that's the gas
23 chromatography testing?
24 A. That is correct, sir.

Page 525

[REDACTED]

Page 527

[REDACTED]

Page 526

[REDACTED]

Page 528

[REDACTED]

5 Q. Were you aware that other
6 Teva facilities were testing valsartan
7 API for DMF?
8 A. I don't think so.
9 Q. Okay. Is there a standard
10 operating procedure in place at Teva to
11 ensure that testing of the residual
12 solvents of a valsartan API at one
13 facility would also be done at another
14 sister facility of Teva's?
15 MS. LOCKARD: Objection to
16 the question and the phrase
17 "sister facility."
18 THE WITNESS: I am aware
19 that wherever valsartan API and
20 valsartan finished product is to
21 be received, in the case of the
22 API used, and the manufacturer in
23 the case of the finished product,
24 the specifications that have to be

<p>Page 529</p> <p>1 complied with are the 2 specifications that have been 3 submitted with the ANDA. 4 BY MR. STANOCH: 5 Q. If one Teva facility was 6 testing valsartan API for DMF because of 7 its potential to contribute to a 8 genotoxic impurity, don't you think 9 that's important information that should 10 have been shared with other Teva 11 facilities that were also receiving and 12 testing valsartan API? 13 MS. LOCKARD: Objection. 14 Vague. 15 THE WITNESS: I am -- I do 16 not know if you're speaking about 17 a theoretical situation or an 18 actual situation. 19 BY MR. STANOCH: 20 Q. Well, let's say -- let's say 21 if one Teva facility is actually testing 22 valsartan API for DMF because of its 23 potential to contribute to a genotoxic 24 impurity, wouldn't it be best practice to</p> <p>Page 530</p> <p>1 have other Teva facilities also sourcing 2 valsartan API to do the same thing? 3 MS. LOCKARD: Objection. 4 Form. Vague. 5 If you have a document that 6 you want to specifically direct 7 him to and ask him about it, that 8 would be helpful to resolve my 9 objection. 10 MR. STANOCH: Go ahead, sir. 11 THE WITNESS: Again, I'd 12 like to make the distinction 13 between a theoretical situation 14 and an actual situation. 15 And at this point I'm not 16 able to -- I mean, I could speak 17 on a theoretical basis, but I just 18 want to make sure that I can 19 answer as accurate as possible. 20 BY MR. STANOCH: 21 Q. That's fair. 22 Let's talk from a process -- 23 a standard operating procedure or process 24 standpoint, okay.</p>	<p>Page 531</p> <p>1 Did Teva have a process in 2 place to ensure that if one facility was 3 testing valsartan API for DMF because of 4 potential genotoxic risk, that other 5 facilities would be notified of that? 6 A. I think we have to take this 7 on a case-by-case basis. Let's assume 8 for a moment, and this is all 9 theoretical, counsel, that one site is 10 doing a specific local investigation for 11 whatever reason, you -- under normal 12 conditions, the sharing would be more on 13 the findings of that investigation, which 14 would follow a process whereby you would 15 raise what we call an NTM and then that 16 NTM would be assessed. 17 So there may be instances 18 where somebody might have said, let's 19 test this, and the outcome of that 20 testing was -- resulted in nothing. So 21 that's why I'm saying that -- I'm trying 22 to understand what the scenario -- if 23 it's a real scenario that we're working 24 with or if it's -- if you're asking me a</p> <p>Page 532</p> <p>1 theoretical question. 2 Q. I appreciate that. 3 Again, the question was 4 focused on whether Teva had a standard 5 operating procedure to ensure sharing of 6 information about testing something like 7 DMF, because of genotoxic potential, in a 8 valsartan API at one facility versus 9 another. 10 MS. LOCKARD: But my 11 objection still stands. Because 12 you're not specifying if this is 13 facility-to-facility comparison 14 for a facility that makes the drug 15 for distribution in the U.S. under 16 the FDA regulations, are you 17 comparing the facility that's 18 got -- governed by an entirely 19 different regulatory scheme and, 20 you know, regulatory submission. 21 I mean, that's my problem with the 22 question. 23 MR. STANOCH: I'm asking the 24 witness, who is designated on</p>
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<p style="text-align: right;">Page 533</p> <p>1 SOPs, if he's aware of an SOP that 2 would cover the sharing of 3 information about testing for DMF 4 because of genotoxic impurity in 5 valsartan API at one Teva facility 6 with other Teva facilities. 7 If he doesn't know if such a 8 policy exists or can't say, he can 9 say that. 10 THE WITNESS: Counsel, I'll 11 answer your question. 12 BY MR. STANOCH: 13 Q. Thank you. 14 A. As I indicated to you, if, 15 in the process of performing a local 16 investigation, a site concludes that its 17 finding with respect to a product 18 manufacture at the site that is also 19 manufactured at another site, the 20 procedures in place indicate that you 21 would escalate this type of information 22 through what is called the NTM process. 23 So there is a process in 24 place whereby that type of information,</p>	<p style="text-align: right;">Page 535</p> <p>1 notification to management procedure, and 2 then whether or not those criteria would 3 be met would be something one would 4 evaluate? 5 A. That is correct. 6 Q. Would you expect Teva to 7 receive, from its API vendors, copies of 8 FDA Form 483s from FDA inspections of 9 that vendor? 10 A. My expectation would be if 11 those FDA 483 observations are directly 12 or somewhat indirectly linked to the 13 product that we have been supplied, I 14 would expect them to share that 15 information with us in order for us to do 16 our own assessment. So yes. 17 Q. So if the FDA issued a Form 18 483 to ZHP that touched on valsartan API, 19 it would have been Teva's expectation to 20 receive at least notice of that from ZHP? 21 A. Correct. 22 Q. And then Teva could take its 23 own steps as -- its own procedures about 24 what to do by way of follow up?</p>
<p style="text-align: right;">Page 534</p> <p>1 if it were to -- if it needed to be 2 escalated, that escalation would lead 3 to -- the NTM process would lead to the 4 dissemination of that discussion with the 5 affected sites. So the process is in 6 place, yes. 7 Q. And when you say "NTM," what 8 does that mean? 9 A. Notification to management. 10 So it's a notification -- it's an 11 escalation process. 12 Q. Got it. 13 So the Teva process or 14 procedure on notifications to management 15 would be applicable in this instance that 16 we've been talking about? 17 A. If the discussion of the 18 issue is raised to the point that it 19 needs to be escalated. So it has to meet 20 certain criteria. Not everything that is 21 assessed is escalated. That's what I'm 22 trying to say. 23 Q. Understood. And so the 24 procedure we would be looking at is the</p>	<p style="text-align: right;">Page 536</p> <p>1 A. Now, keep in mind -- I'd 2 like to clarify. 3 The site that is receiving 4 the FDA 483 has options to describe the 5 situation to us, not necessarily to share 6 a copy of the 483. There are other 7 factors involved. 8 So they might say, you know, 9 with respect to your product, this is 10 what the areas -- so I just want to 11 clarify that it's not as simple as them 12 sharing an FDA 483 with us, because that 13 may contain, also, information for other 14 clients that they don't want to divulge. 15 So there's a policy around 16 that, you know, in general. 17 Q. I understand. 18 And it may be that an API 19 supplier that receives a Form 483, 20 instead of sharing the whole 483 with 21 Teva, it may redact it, or it may simply 22 give another type of communication 23 without attaching it to Teva; that would 24 be Teva's expectation?</p>

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1 A. That is correct.
2 Q. I understand.
3 But the fact that the FDA
4 issued the Form 483, if it touched on a
5 product that Teva was purchasing, it
6 would still be the expectation of Teva to
7 learn about that, right?
8 A. In general, yes.
9 Q. And are you aware of whether
10 or not ZHP ever informed Teva about an
11 FDA 483 issued to it in connection with a
12 2017 FDA inspection of the Chuannan site?
13 A. I believe we knew about it.
14 Q. Do you recall whether Teva
15 learned about it before or after June
16 2018?
17 A. I believe it was before June
18 2018, because we keep track of all the
19 inspections.
20 Q. And what is it that makes
21 you think that you received -- that Teva
22 received a notice of that, prior to June
23 2018, from ZHP?
24 A. Because through the vendor

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1 quality program, we are in constant
2 communication with suppliers. So we know
3 when they are being inspected. That
4 information is shared.
5 Q. And who would have gotten
6 that communication from ZHP about the FDA
7 483 from the 2017 FDA inspection?
8 A. That would have been, more
9 than likely, our supply chain group along
10 with that communication coming down to
11 the quality group that works with vendor
12 quality.
13 Q. Do you recall whether that
14 Form 483 that the FDA issued to ZHP in
15 2017, whether it related in any way to
16 valsartan API or not?
17 A. I think there was -- there
18 may have been some reference to it. I
19 don't recall well now. But I think there
20 was some reference to it.
21 Q. Did Teva do anything in
22 response to the FDA Form 483 observations
23 from its 2017 inspection in its own
24 audits of ZHP in May of 2018?

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1 A. I don't specifically recall,
2 but I don't think that there was a need
3 to do anything because the findings from
4 the inspection did not require anything
5 for Teva to do.
6 Q. Do you understand that the
7 FDA's Form 483 from its 2017 inspection
8 of ZHP touched on unknown peaks in
9 chromatograms for valsartan API?
10 A. I do.
11 Q. And Teva didn't address that
12 specifically in its audit of ZHP in May
13 2018, did it?
14 A. It may have looked at it,
15 and it may not have concluded that this
16 was anything that was of relevance.
17 The finding of unknown
18 peaks, especially in API facilities, it's
19 quite a common situation. So when you
20 find these peaks, what we also -- what we
21 do is we actually look at the extent to
22 which the investigations that were
23 performed were adequate in terms of the
24 root cause analysis.

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1 So unknown peaks is pretty
2 routine. So the fact that you have
3 unknown peaks, that does not necessarily
4 translate into an interpretation that you
5 may or may not have, let's say,
6 nitrosamines.
7 Q. Right. Well, the fact that
8 there are unknown peaks, you would expect
9 that there would be an investigation into
10 the cause of that, correct?
11 A. And there was, yes, based on
12 our knowledge.
13 Q. Right. Well -- but when the
14 FDA inspection happened of ZHP in 2017
15 and Teva was at the same ZHP facility in
16 May 2018, there's no mention of those FDA
17 findings about the unknown peaks in the
18 valsartan API in Teva's audit report, is
19 there?
20 A. There may not have been. I
21 don't recall now the specifics of what --
22 but that does not necessarily mean that
23 we would follow up on every one of the
24 observations made by the FDA.

<p>Page 541</p> <p>1 Keep in mind that ZHP 2 submitted a response to the FDA, and that 3 response seems to have been found 4 acceptable to the FDA. 5 So when it comes, again, to 6 the type of audits that we do, our focus 7 is going to be based on a number of 8 different, let's say, priorities that we 9 have with respect to what we're going to 10 look at. 11 So the fact that we may not 12 have followed up, that does not mean that 13 it was because we, let's say, didn't find 14 that to be necessary. If it was just -- 15 in my opinion, based on my knowledge, 16 unknown peaks is not necessarily a reason 17 to be overly cautious about, you know, 18 the assessment of a supplier. 19 MS. LOCKARD: I just want to 20 say, too, just out of basic 21 fairness. If you're going to ask 22 him about findings in the May 2018 23 audit, I'd like him to be able to 24 look at that document.</p> <p>Page 542</p> <p>1 I mean, we've confirmed that 2 it's not intended to be a memory 3 test. 4 So do you have that 5 available to pull up? 6 MR. STANOCH: I'll ask my 7 questions, and you can ask him 8 questions. He testified already. 9 It's fine. 10 MS. LOCKARD: Excuse me, 11 then. I'm objecting to you asking 12 him questions about documents that 13 you're not willing to show him. 14 MR. STANOCH: I didn't say 15 that. The witness didn't ask for 16 it. Your objection is noted. 17 BY MR. STANOCH: 18 Q. Mr. Barreto, are you aware 19 of any specific follow-up that Teva did 20 with ZHP, prior to June 2018, about 21 unknown peaks in valsartan API 22 chromatograms that the FDA had identified 23 in its 2017 inspection? 24 MS. LOCKARD: And just</p>	<p>Page 543</p> <p>1 because of that cutoff, if you 2 need to look at any documents, you 3 can. 4 THE WITNESS: I'd like to 5 look at it, if that's possible, 6 counsel. 7 But my recollection of that 8 is that the auditors would look at 9 issues that they will deem in the 10 field to be any issues that they 11 want to cover. 12 But I think what -- but I 13 also want to clarify that the fact 14 that FDA had some observations 15 with respect to unknown peaks in 16 that there was a response, that 17 does not necessarily trigger the 18 need for our auditors to pursue 19 the FDA inspection. 20 BY MR. STANOCH: 21 Q. Is it Teva's policy not to 22 follow up with its API vendors on all 23 observations in FDA 483s of that vendor? 24 A. I have to look at the</p> <p>Page 544</p> <p>1 policy, if you want to share it with me. 2 But the policy, it's a 3 guidance document that still lets the 4 auditor make a decision as to where he or 5 she wants -- or they want to go in the 6 performance of their audit. 7 So it is -- it is -- it is a 8 recommendation that people look at 9 observations, but that does not 10 necessarily mean they have to do it. 11 Q. Do you recall, as head of 12 quality in 2018, instructing any Teva 13 auditors to follow up at ZHP about the 14 unknown chromatogram peaks in valsartan 15 API that the FDA had identified at ZHP? 16 A. I don't remember doing that. 17 But I do remember, once the issue was 18 discovered, we put together a series of 19 instructions to the auditors on 20 activities they needed to pursue. 21 Q. That was after June 2018, 22 before the for-cause audit in the fall; 23 is that correct? 24 A. That is correct.</p>
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1 MR. STANOCH: One moment,
2 sir, while I try to get an
3 exhibit.
4 THE WITNESS: Yes.
5 MR. STANOCH: This was
6 previously marked as Teva-61, sir.
7 One moment while I try to publish
8 it to you.
9 THE WITNESS: Yes. Thank
10 you.
11 MR. STANOCH: Amanda, what
12 did I just say, that it was
13 previously marked Teva Exhibit-61?
14 COURT REPORTER: Correct.
15 MR. STANOCH: Thank you.
16 Sorry, I have to manually number
17 these. So I don't want to make a
18 mistake. Thank you.
19 BY MR. STANOCH:
20 Q. Sir, let me know when you
21 see it.
22 MR. STANOCH: I'll just
23 state, meanwhile, for the record,
24 Exhibit Teva-61 was previously

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1 marked. It's Bates number ending
2 118147.
3 THE WITNESS: Let me refresh
4 here to see if I can see it.
5 BY MR. STANOCH:
6 Q. Sure.
7 A. Okay. I see 61 here.
8 Yes.
9 Q. You're familiar with this
10 document, sir?
11 A. Yes.
12 Q. Right. This is the audit
13 report from Teva's audit of ZHP's site
14 that was making valsartan API. The audit
15 date was May 21 through May 25, 2018?
16 A. Correct.
17 Q. Teva had auditors on the
18 ground at ZHP mere weeks before it found
19 out about the nitrosamine contamination
20 issue, right?
21 A. Yes.
22 Q. Do you know if the
23 nitrosamine contamination issue was
24 discussed at all during Teva's audit of

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1 ZHP in May 2018?
2 A. I'm sure that was not the
3 case.
4 Q. And you can -- you can look
5 through the document, sir, but I'm not
6 seeing any reference to -- strike that.
7 Sir, you can look through
8 the document, I'm not seeing reference to
9 any discussion between the Teva auditors
10 and ZHP, during this audit, about the FDA
11 Form 483.
12 You can take a moment to
13 look through it, and I'm doing a word
14 search --
15 A. Yeah. I'm looking for it.
16 But, again, the auditors -- the purpose
17 of the audit is for the auditors to take
18 a look at the state of compliance of a
19 site at the time when the audit is
20 performed.
21 So it is good information to
22 have findings from the FDA, if the
23 auditor deems those to be good for them
24 to follow up.

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1 But the core -- the core
2 objective of the audit is for that
3 auditor to determine the state of
4 compliance of that site in May 2018,
5 based on the evaluations that they do of,
6 you know, incoming materials, in-process
7 control activities, the manufacturing
8 process, cleaning activities, OOSs that
9 would be applicable to be reviewed
10 because they are based on our product,
11 any deviations that are associated with
12 the production of our product.
13 So -- so the fact that they
14 may or may not have covered, in this
15 case -- and I'm still looking -- it does
16 not mean that the audit is less relevant
17 for the purpose of determining the
18 compliance of that site.
19 MS. LOCKARD: And just for
20 completion of the record, there is
21 reference to the May 2018
22 inspection.
23 MR. STANOCH: Well, counsel,
24 are you going to testify now? I

<p style="text-align: right;">Page 549</p> <p>1 just --</p> <p>2 MS. LOCKARD: No, but I --</p> <p>3 MR. STANOCH: -- told the</p> <p>4 witness he can look at the</p> <p>5 document.</p> <p>6 MS. LOCKARD: Excuse me.</p> <p>7 MR. STANOCH: That's</p> <p>8 improper. That's improper, Ms.</p> <p>9 Lockard.</p> <p>10 MS. LOCKARD: You -- it's</p> <p>11 improper for you to tell him you</p> <p>12 just searched the document and you</p> <p>13 found nothing.</p> <p>14 I haven't told him anything.</p> <p>15 All I'm saying is if you're not</p> <p>16 using the correct search terms,</p> <p>17 you're not going to find it.</p> <p>18 MR. STANOCH: What search</p> <p>19 term are you using, counsel?</p> <p>20 MS. LOCKARD: If you want to</p> <p>21 get to the truth, that's one</p> <p>22 thing. That's what we're here</p> <p>23 for. If you want to mislead him</p> <p>24 and tell him it's not in here</p>	<p style="text-align: right;">Page 551</p> <p>1 follow-up to the observations, I</p> <p>2 don't think that was the case.</p> <p>3 And what I'm saying to you</p> <p>4 is, if it was not the case -- and</p> <p>5 it may have been, I need to</p> <p>6 look -- review the document</p> <p>7 completely.</p> <p>8 If it was not the case, that</p> <p>9 does not necessarily mean that the</p> <p>10 objectives of the audit were not</p> <p>11 met.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Sir, I understand</p> <p>14 completely. And you and I were on the</p> <p>15 same page. Your counsel was not.</p> <p>16 If you want more time to</p> <p>17 look at this document to double check or</p> <p>18 double confirm what you just said, go</p> <p>19 ahead. But, otherwise, I'm ready to move</p> <p>20 on. So you tell me, sir.</p> <p>21 A. Just allow me a second to go</p> <p>22 through.</p> <p>23 Q. Sure.</p> <p>24 A. Thank you, counsel.</p>
<p style="text-align: right;">Page 550</p> <p>1 because you did not find it</p> <p>2 searching --</p> <p>3 MR. STANOCH: I told him to</p> <p>4 look at the document and tell me</p> <p>5 where it mentions 483 observations</p> <p>6 from the FDA. I told him to do</p> <p>7 that and said take your time.</p> <p>8 I don't appreciate what</p> <p>9 you're doing, counsel, in</p> <p>10 testifying.</p> <p>11 THE WITNESS: Counsel, I'm</p> <p>12 looking at Section 1.3, where it</p> <p>13 makes reference to those</p> <p>14 inspections. And I've seen this</p> <p>15 before, and it's typical.</p> <p>16 But I think that what I</p> <p>17 thought you were asking us -- me</p> <p>18 to look at, counsel, was whether</p> <p>19 or not there was a follow-up.</p> <p>20 So there is discussion about</p> <p>21 it. But I don't necessarily -- I</p> <p>22 mean, in the browsing that I've</p> <p>23 done of this extensive document,</p> <p>24 if they look at these, you know,</p>	<p style="text-align: right;">Page 552</p> <p>1 Q. Take your time, as much as</p> <p>2 you need, sir.</p> <p>3 A. Thank you, I appreciate it.</p> <p>4 I'm almost done.</p> <p>5 Q. That's fine. Take your</p> <p>6 time, sir.</p> <p>7 A. Thank you.</p> <p>8 So I couldn't find any</p> <p>9 specific references. Now, this is also a</p> <p>10 redacted document, so it could have been</p> <p>11 that the auditors may have covered</p> <p>12 something in those documents -- in those</p> <p>13 redacted areas associated with</p> <p>14 impurities.</p> <p>15 I cannot tell you because</p> <p>16 I'm not privy to that information at this</p> <p>17 point.</p> <p>18 Q. That's fair.</p> <p>19 You understand, though, that</p> <p>20 I didn't make those redactions, Teva did,</p> <p>21 right?</p> <p>22 A. Yes.</p> <p>23 Q. Thank you.</p> <p>24 MR. STANOCH: Why don't we</p>

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1 go off the record for a couple of
2 minutes?
3 THE WITNESS: Okay.
4 VIDEO TECHNICIAN: The time
5 is now 10:54 a.m. Going off the
6 record.
7 - - -
8 (Whereupon, a brief recess
9 was taken.)
10 - - -
11 VIDEO TECHNICIAN: The time
12 is now 11:14 a.m. Back on the
13 record.
14 BY MR. STANOCH:
15 Q. Mr. Barreto, did Teva have a
16 policy, prior to July 2018, to ensure
17 that Teva's API suppliers complied with
18 their obligations to send notification of
19 adverse regulatory inspections to Teva?
20 A. I would have to check on
21 that. I don't recall. I would have to
22 check on that, counsel.
23 Q. You're not sure?
24 A. I'm not sure.

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1 Q. Did Teva have a policy,
2 prior to July 2018, requiring Teva's own
3 auditors to follow up with API suppliers
4 about FDA inspections of those suppliers?
5 A. Prior to 2017, I don't
6 recall that policy.
7 But, again, but, routinely,
8 auditors would make that decision based
9 on the finding for the audit.
10 Q. I might have misspoke or
11 maybe you misheard. My question was
12 about July 2018.
13 So I'm just going to say it
14 again, and you can say your answer, okay.
15 Did Teva have a policy,
16 prior to July 2018, requiring Teva's own
17 auditors to follow up with API suppliers
18 about FDA inspections of those suppliers?
19 A. And the answer is, I don't
20 recall if that policy exists.
21 However, the practice would
22 be for auditors to look into whether or
23 not they need to follow up on those
24 audits.

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1 Q. Did Teva have a policy,
2 prior to July 2018, to conduct its own
3 due diligence to ascertain whether Teva's
4 API suppliers had received any adverse
5 regulatory findings such as FDA 483s?
6 A. I know that prior to 2017 we
7 had the processes in place, regulatory
8 intelligence activities, whereby any
9 inspections generated and the findings of
10 those inspections would be collected and
11 disseminated across the organization.
12 Q. And, again, I think you said
13 2017.
14 So is it the same answer for
15 prior to July 2018?
16 A. I think so, yes.
17 Q. For example, did Teva have a
18 policy or practice, prior to July 2018,
19 to regularly review the FDA's public
20 website for regulatory findings about a
21 Teva API supplier?
22 A. Certainly the practice was
23 there. And one of the reasons for that
24 is that in the development of corporate

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1 standards, we are constantly looking at
2 any trends or new expectation from the
3 agency.
4 MR. STANOCH: One moment,
5 I'm just going to put a new
6 exhibit in front of you, sir.
7 THE WITNESS: Yes.
8 BY MR. STANOCH:
9 Q. Yesterday we talked about
10 quality agreements, and I think you said
11 you had seen one or more agreements
12 between a legacy Actavis entity and ZHP,
13 correct?
14 A. I think I said that, yes.
15 Q. And I just want to put a
16 couple of documents in front of you for
17 you to confirm whether or not they would
18 be the operative agreements, okay?
19 A. That would be okay.
20 MR. STANOCH: So this will
21 be Teva-167.
22 - - -
23 (Whereupon, Exhibit
24 Teva-167, TEVA-MDL2875-00020279,

<p>Page 557</p> <p>1 3/24/16 Quality Agreement, was 2 marked for identification.) 3 - - - 4 BY MR. STANOCH: 5 Q. Tell me when you have it. 6 A. I'm opening it as we speak. 7 MR. STANOCH: Bates ending 8 20279, for the record. 9 THE WITNESS: That is 10 correct. 11 BY MR. STANOCH: 12 Q. And this appears to be a 13 quality agreement for active 14 pharmaceutical ingredient, date of issue, 15 March 24th, 2016? 16 A. Yes. 17 Q. It appears to be between an 18 Actavis entity in Iceland and ZHP, 19 correct? 20 A. That is correct. 21 Q. And as far as you know, was 22 this the operative agreement between 23 Actavis and ZHP, at least as of the date 24 of this agreement being signed?</p> <p>Page 558</p> <p>1 The signatures, you can look 2 at on Page 14, which are in March and 3 April of 2016. 4 A. So that would be the 5 agreement between that organization 6 within Actavis and ZHP. 7 Q. And among the APIs that were 8 subject to this agreement, are those 9 listed in Appendix 2? 10 And you can go through, but 11 I'll tell you that Row Number 48 12 identifies valsartan, if you want to look 13 at that and confirm. 14 A. Allow me for a second, 15 please. 16 Yes, sir. Number 48. 17 Q. Thank you. 18 And it's your 19 understanding -- well, would it be your 20 understanding that this is the 21 agreement -- well, strike that. 22 Once Actavis was integrated 23 into Teva, do you know if there was a new 24 agreement that superceded any legacy</p>	<p>Page 559</p> <p>1 Actavis agreement with ZHP for the 2 procurement of API? 3 A. I'm not so sure that the 4 superceding would necessarily happen 5 immediately. Quality agreements remain, 6 you know, for as long as there's the 7 relationship between the organizations, 8 independent of whether or not that 9 organization belongs to another one. 10 So quality agreements do not 11 necessarily have, like, an expiration 12 date. So I would say that quality 13 agreement, more than likely, was the -- 14 was in effect. 15 Q. Got it. 16 And there's no trick here, 17 sir. I'm happy to tell you I haven't 18 found an agreement between legacy Actavis 19 and ZHP that's postdated this one. 20 I guess my question is, are 21 you aware of any quality agreement 22 between legacy Actavis or Teva, for that 23 matter, and ZHP that postdates this 24 agreement?</p> <p>Page 560</p> <p>1 A. I would say, again, I 2 couldn't see the need -- so long as that 3 agreement remains in effect, I would not 4 see a need for another agreement to be in 5 place. 6 MR. STANOCH: I'm going to 7 mark the next exhibit, sir. 8 THE WITNESS: Yes. 9 MR. STANOCH: 168. Bates 10 ending 20213. 11 - - - 12 (Whereupon, Exhibit 13 Teva-168, TEVA-MDL2875-00020213, 14 Technical Agreement Between 15 Actavis Group and Zhejiang Huahai, 16 was marked for identification.) 17 - - - 18 BY MR. STANOCH: 19 Q. You can take -- you can take 20 time to look at it. 21 But in the meantime, I'll 22 state it appears to be a technical 23 agreement between an Actavis entity and 24 ZHP. This one is dated June 15th, 2012,</p>
--	--

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1 so a few years earlier than the one we
2 just looked at.
3 But take a moment and just
4 confirm all that for me.
5 A. Yes, I'm looking at it.
6 Q. This appears to be the
7 agreement between a legacy Actavis entity
8 and ZHP, effective in 2012 through the
9 effects of the more recent agreement that
10 we just looked at in the previous
11 exhibit; is that fair?
12 A. That's fair.
13 And I think what I'd like to
14 clarify, if possible, if we could go back
15 to the previous document.
16 Q. Sure.
17 A. This one says, Revision 2.
18 So, therefore, there was a
19 Revision 1 and, perhaps, a Revision Zero,
20 the original document.
21 So what happens is that
22 these documents are updated on a certain
23 basis, whenever it's necessary. So I
24 think that's the case here, counsel.

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1 Q. I'm fine -- I'm fine with
2 your answer, sir, and don't need to go
3 back.
4 But if you want to go back
5 to the last exhibit to look at it, feel
6 free and tell me.
7 A. Yeah, I'm doing that.
8 So, yeah, yep. This one,
9 again, there may have been changes in
10 terms of the way in which -- this one
11 says Version 1.0. So there -- we would
12 have to look at the history.
13 Q. And then there is --
14 MR. STANOCH: I'm going to
15 mark another exhibit, 169. For
16 the record, it's Bates ending
17 20214.
18 - - -
19 (Whereupon, Exhibit
20 Teva-169, TEVA-MDL2875-00020214,
21 Amendment to Quality Agreement,
22 was marked for identification.)
23 - - -
24 BY MR. STANOCH:

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1 Q. And you can look at it, sir,
2 but it appears to be an amendment to the
3 quality agreement from 2012 between
4 Actavis and ZHP.
5 A. Correct. Correct.
6 Q. And, again, in this one,
7 under manufacturing, it lists one of the
8 APIs subject to the agreement -- that
9 agreement, as valsartan, right?
10 A. That's what the document
11 says, yes.
12 MR. STANOCH: I'm going to
13 mark another exhibit, sir.
14 - - -
15 (Whereupon, Exhibit
16 Teva-170, TEVA-MDL2875-00020212,
17 Quality Agreement for Active
18 Pharmaceutical Ingredient, was
19 marked for identification.)
20 - - -
21 MR. STANOCH: This one will
22 be Teva Exhibit-170, Bates ending
23 20212.
24 THE WITNESS: Allow me to

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1 upload it, please.
2 Yes, sir.
3 BY MR. STANOCH:
4 Q. And this appears to be a
5 quality agreement for active
6 pharmaceutical ingredient between Arrow
7 Pharm, Malta, and Zhejiang Huahai,
8 correct?
9 A. That is correct.
10 Q. And it looks as if it's
11 dated by both parties; ZHP signing May
12 28th, 2011, and Arrow Labs signing June
13 10th, 2011.
14 Do you see that?
15 A. I'm looking at that.
16 Yes, sir.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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[REDACTED]

13 A. That's correct.

14 MR. STANOCH: I'm going to

15 hand you another exhibit, sir.

16 THE WITNESS: Yes, sir.

17 MR. STANOCH: One moment,

18 please. This is Teva-172, sir.

19 Bates ending 24488.

20 - - -

21 (Whereupon, Exhibit

22 Teva-172,

23 TEVA-MDL2875-00024488-4492,

24 11/13/19 E-mail, Barreto to Drape,

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[REDACTED]

24 our strategy.

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1 was marked for identification.)

2 - - -

3 THE WITNESS: Allow me to

4 refresh and upload it.

5 BY MR. STANOCH:

6 Q. Sure. Let me know when you

7 have it and when you've had a moment to

8 review it.

9 A. I have it.

10 MR. STANOCH: While you

11 review it, I'll state for the

12 record that it appears to be an

13 e-mail from you, dated November

14 13th, 2019, to Mr. Drape and

15 others; subject, Nitrosamine news.

16 BY MR. STANOCH:

17 Q. When you're ready, tell me

18 if that's right.

19 A. That is correct. That's the

20 e-mail.

21 Q. You recall this e-mail

22 chain, right?

23 A. Yes, I do.

24 Q. And it looks like one of

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1 your colleagues was forwarding a
2 third-party communication that included a
3 report about Mylan's valsartan API and
4 nitrosamine impurities?
5 A. Yes.
6 Q. And then Eric Drape wrote,
7 We did a better job than Mylan.
8 Do you see that?
9 A. That is correct.
10 Q. And then you wrote back,
11 Totally agree. None of the observations
12 at any of the sites rose to that level of
13 concern.
14 Do you see that?
15 A. That's correct.
16 Q. What were you agreeing
17 with -- strike that.
18 Why were you agreeing with
19 Mr. Drape that we -- which I assume is
20 Teva -- did a better job than Mylan?
21 A. Allow me to read it.
22 Because I think I know the answer --
23 Q. Sure.
24 A. -- but allow me to refresh

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1 my memory.
2 Q. Please.
3 A. If I recall this very well,
4 what Mr. Drape was saying -- the word
5 "we," I think what he was referring to
6 was more the fact that ZHP, it appears,
7 did a much better job at whatever he was
8 referring to at the time, based on the
9 input from, you know, the third party.
10 And I'm saying that I
11 totally agree, meaning that none of the
12 observations at any of the sites rose to
13 that level of concern.
14 So it could have been, now
15 that I'm -- I'm sorry, now that I'm
16 looking at this, I think -- sorry, I'd
17 like to correct myself.
18 Q. Please, go ahead.
19 A. I think -- I think he was
20 referring to us at Teva, in terms of the
21 work that we did at our own facilities,
22 meaning API facilities. So this would be
23 the scope of this discussion.
24 Q. The sentiments between you

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1 and Mr. Drape were that Teva had done a
2 better job with the nitrosamine issues in
3 valsartan API than Mylan, as reported in
4 the news stories below?
5 A. Based on the input from that
6 story, that is correct.
7 Q. Stand by.
8 Ultimately, Teva still
9 recalled all of its valsartan product
10 that contained Mylan's valsartan API,
11 right?
12 A. Yes, we did.
13 Q. And Teva did not identify
14 the NDMA or NDEA contamination in that
15 Mylan valsartan API prior to November
16 2018, right?
17 A. No, we did not.
18 Q. But you still believe that
19 Teva did a better job than Mylan?
20 MS. LOCKARD: Objection to
21 form.
22 MR. STANOCH: Withdrawn.
23 Teva-173, sir.
24 - - -

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1 (Whereupon, Exhibit
2 Teva-173,
3 TEVA-MDL2875-00024041-4045,
4 3/27/19 E-mail, Vanderweeen to
5 Barreto, was marked for
6 identification.)
7 - - -
8 THE WITNESS: Yes, just give
9 me a moment.
10 MR. STANOCH: For the
11 record, this is be Bates 24041.
12 THE WITNESS: Yes, sir.
13 BY MR. STANOCH:
14 Q. This appears to be an e-mail
15 chain, topmost message from Birk
16 Vanderweeen, March 27, 2019, to yourself
17 and others, regarding FDA decision on
18 sartans?
19 A. That's correct.
20 Q. Do you recall being part of
21 this e-mail chain?
22 A. I do.
23 Q. It looks like this e-mail
24 chain is discussing whether or not Teva

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1 can release valsartan finished products
2 that might not meet the FDA's interim
3 limits in other countries; is that right?
4 A. Allow me to read it quickly.
5 Q. Sure.
6 A. Yes.
7 What is your question,
8 counsel?
9 Q. I think my question was, it
10 appears that Teva was discussing whether
11 or not it could sell valsartan
12 finished-dose products in other countries
13 when that product might contain NDMA
14 that's above the FDA interim limits?
15 A. Yes. And the concern at the
16 time was to ensure that we could supply
17 medication to the patient based on the
18 specific expectations that would be set
19 by the specific countries.
20 So these are countries that
21 would be countries other than the
22 European countries, so in the U.S. and
23 Canada. So every -- every country has
24 its own -- had its own expectation for

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1 how they would fulfill patient needs.
2 And this could be whether we
3 could use other sartan products, for
4 instance, irbesartan or losartan, to
5 still fulfill that expectation from a
6 patient perspective.
7 So the concept around this
8 was, we know what we know with respect to
9 each specific country's requirements or
10 limitations or conditions, can we still,
11 on a risk-based approach, provide
12 medication that fulfills the expectations
13 of the patients in specific countries
14 with the understanding that the
15 regulatory bodies in those countries
16 would accept those products.
17 Q. So is it correct that Teva
18 sold valsartan finished dose in other
19 countries besides the United States that
20 they were not able to sell in the United
21 States because the nitrosamine levels
22 might have been above the FDA's interim
23 limits?
24 MS. LOCKARD: Objection.

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1 This is outside the scope of the
2 notice of deposition as it relates
3 to product that was not sold in
4 the United States. It's also
5 outside of the court's discovery
6 order.
7 MR. STANOCH: You can
8 answer.
9 MS. LOCKARD: And it calls
10 for speculation.
11 THE WITNESS: Do you want me
12 to answer the question?
13 MS. LOCKARD: If you can.
14 THE WITNESS: The answer to
15 the question is that we sold, in
16 other countries, products that
17 were deemed to be acceptable, in
18 the middle of the situation, by
19 those other countries.
20 So there was a discussion
21 with each specific country with
22 respect to whether or not we could
23 be allowed to sell these products.
24 So the concern was to ensure

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1 that we could fulfill patient
2 need.
3 BY MR. STANOCH:
4 Q. Again, so a valsartan
5 product that had nitrosamines above the
6 FDA interim limits was sold by Teva in
7 certain foreign countries; is that right?
8 MS. LOCKARD: Objection.
9 Same objections I just stated.
10 MR. STANOCH: You can
11 answer.
12 THE WITNESS: The answer is
13 that in discussions with the
14 regulatory authorities of specific
15 countries, given that the
16 situation changed from country to
17 country, and each country had set
18 its own interim limits, wherever
19 specific limits that were
20 acceptable to those countries
21 applied for certain batches, after
22 discussion with those countries,
23 we would supply those countries
24 with product that would fulfill

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1 those expectations.
2 BY MR. STANOCH:
3 Q. So even though Teva couldn't
4 sell product with certain nitrosamine
5 levels in the United States, it tried to
6 find countries in which it could sell
7 that product, and did, in fact, do so,
8 right?
9 MS. LOCKARD: Objection.
10 Misstates the evidence.
11 THE WITNESS: I continue to
12 indicate that the release of
13 product to other countries is
14 independent from the release of
15 product to the United States,
16 because the expectations set by
17 those countries for those products
18 is what we were expected to
19 fulfill, based on the
20 understanding that each country
21 was looking at a patient
22 risk/benefit ratio for their
23 specific patients.
24 MR. STANOCH: I'm going to

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1 mark another exhibit, sir.
2 Exhibit-174. Bates ending
3 495893.
4 - - -
5 (Whereupon, Exhibit
6 Teva-174,
7 TEVA-MDL2875-00495893-5896,
8 3/27/19 E-mail, Vanderween to
9 Barreto, was marked for
10 identification.)
11 - - -
12 THE WITNESS: Allow me to
13 upload it, and I'll be there with
14 you.
15 Yes, counsel.
16 BY MR. STANOCH:
17 Q. This appears to be an e-mail
18 chain, topmost message from Birk
19 Vanderween again, March 27, 2019, to
20 you, Mr. Sawyer, Mr. Drape; is that
21 right?
22 A. That is correct.
23 Q. And you can review it, but
24 when you're done reviewing it, the

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1 question is, again, this relates to
2 Teva's discussions about where it can
3 sell valsartan products that might be
4 over certain nitrosamine levels in one
5 country but not others.
6 MS. LOCKARD: Objection to
7 the form of the question. It's
8 outside the scope of the notice of
9 the deposition. And it's outside
10 of the court discovery order to
11 the extent it involves product not
12 sold in the United States.
13 THE WITNESS: I think
14 counsel is -- are you waiting on
15 me?
16 BY MR. STANOCH:
17 Q. I was waiting on you to
18 answer the question after you had a
19 moment to review the document.
20 A. My apologies.
21 Q. No problem.
22 A. So I continued to reaffirm
23 that the shipment of product, at the time
24 of this discussion, as this issue was --

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1 evolved, would only occur after
2 discussions with the specific regulatory
3 authorities, based on whatever allowance
4 we could get from them.
5 The same actually applied in
6 the United States where, you know, there
7 were instances where the FDA put that
8 interim specification to allow certain
9 product to be -- certain lots to be
10 shipped to the United States, even though
11 the FDA knew that there were certain --
12 so this is an evolving process.
13 And that interim
14 specification was established as a
15 tolerance to allow for certain product
16 containing -- so it's not like we did
17 this for other countries and not to the
18 United States. The FDA provided that
19 tolerance level that would bring that
20 patient that -- a risk/benefit ratio for
21 the patient.
22 Q. And there's also reference
23 in here that there is no case at the
24 moment to bring back valsartan from

<p>Page 589</p> <p>1 Huahai. 2 Do you see that in Mr. 3 Sharvas's e-mail of March 25th, 2019? 4 A. Just a moment. Same e-mail? 5 Q. It was the March 29th, 2019, 6 9:29 p.m., message on the second page, 7 the bottom. 8 A. Yes, okay. Let me go there. 9 And what is the question, 10 counsel? 11 Q. Is it correct, to your 12 understanding, that as of March 2019, 13 Teva still could not sell product using 14 ZHP's valsartan API in the United States 15 because of the continuing nitrosamine 16 issues? 17 A. Let me read it again. 18 That may have been the case. 19 Again, because of the situation where we 20 were dealing with the impurity 21 specification, the interim 22 specifications. So, of course, we had 23 very strong discussions as to whether or 24 not we would be able to -- with the</p> <p>Page 590</p> <p>1 information that we had about the 2 valsartan batches, whether we had any 3 product that could fulfill those 4 expectations. That was the discussion. 5 MR. STANOCH: Why don't we 6 take a quick break? 7 THE WITNESS: Yes, counsel. 8 VIDEO TECHNICIAN: The time 9 is 11:57 a.m. Going off the 10 record. 11 - - - 12 (Whereupon, a luncheon 13 recess was taken.) 14 - - - 15 VIDEO TECHNICIAN: The time 16 is now 1:22 p.m. Back on the 17 record. 18 BY MR. STANOCH: 19 Q. Welcome back, Mr. Barreto. 20 Other than being part of the 21 Teva group who worked on the preparation 22 of the valsartan recall notices that Teva 23 issued, did you have any direct 24 communications, oral or written, with any</p>	<p>Page 591</p> <p>1 of Teva's valsartan finished-dose 2 customers in the U.S.? 3 A. I would not have direct 4 communication with finished drug 5 customers. That would be somebody else's 6 responsibility. 7 Q. For instance, you would not 8 know about whether communications from a 9 wholesaler, such as McKesson, and Teva 10 occurred concerning the recalls, other 11 than maybe the recall notice; is that 12 fair? 13 A. That is fair. I would not 14 have any knowledge of that type of 15 interaction. 16 Q. And would that be fair for 17 any wholesaler customer of Teva, not just 18 McKesson? 19 A. That is correct. 20 Q. How about communications 21 with retail pharmacies; did you have any 22 direct communications, oral or written, 23 with retail pharmacies concerning Teva's 24 valsartan finished dose?</p> <p>Page 592</p> <p>1 A. No. 2 Q. Okay. And that's not 3 something you prepared to discuss today, 4 correct? 5 A. No. 6 Q. And you did not prepare to 7 discuss today specific communications, if 8 any, that Teva had with wholesaler 9 customers concerning Teva's valsartan 10 finished dose; is that fair? 11 A. That's -- yeah. That would 12 be out of my scope of responsibility. 13 Q. Are you aware of any 14 communications from one of Teva's 15 customers to Teva about the nitrosamines 16 in valsartan API or valsartan finished 17 dose? 18 A. If that communication came 19 down to the quality organization, yes. 20 Q. Are you aware of any such 21 communications sitting here today? 22 A. I may have been. I don't 23 recall, but I may have been. 24 Q. In preparation for today's</p>
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1 deposition, did you review communications
2 from wholesalers to Teva about
3 nitrosamine contamination of finished
4 dose or API valsartan?
5 A. No.
6 Q. Is it fair to say you're not
7 prepared today to talk about the content
8 of communications, if any, between
9 wholesaler customers of Teva that might
10 have related to nitrosamine contamination
11 in finished-dose valsartan or valsartan
12 API?
13 A. I would not be prepared for
14 that.
15 MS. LOCKARD: And just for
16 the record, now that we're on the
17 record, as counsel discussed, we
18 will be -- we've cross-designated
19 another witness for these topics
20 as well.
21 MR. STANOCH: Thank you, Ms.
22 Lockard.
23 BY MR. STANOCH:
24 Q. Sir, when was the first

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1 time, if you know, that Teva informed its
2 customers about the potential nitrosamine
3 impurity in either valsartan finished
4 dose or valsartan API?
5 A. That would be pretty much
6 immediately after -- I would say it was
7 in reasonable time after we had performed
8 an investigation.
9 The reason for that is that
10 as soon as the information becomes -- as
11 soon as it becomes known that there is an
12 issue, our supply chain and customer
13 relationship personnel would
14 immediately -- if you put the product on
15 hold, the question will be asked, why is
16 the product on hold.
17 There is -- there is already
18 some kind of an understanding within the
19 industry that when a product is on hold,
20 something is wrong.
21 So I'm assuming that the
22 immediate hold was that -- triggered that
23 type of communication within the supply
24 chain organization.

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1 Q. Is it your understanding
2 that that communication would have
3 occurred at or shortly after the date of
4 the July 3rd, 2018, field alert to the
5 FDA that we saw earlier?
6 A. I'm sure it must have been
7 more or less right around that same time.
8 Q. And you weren't personally
9 responsible for ensuring all of Teva's
10 customers received notification about the
11 issue, were you?
12 A. We have a process in place
13 whereby, once a decision is made to
14 initiate a recall, communication is
15 prepared to inform our customers. We --
16 you know, again, also working through FDA
17 to inform all of the affected parties.
18 Q. Is it correct that Teva also
19 informed, at or after July 3rd, 2018,
20 U.S. retail pharmacies about the
21 nitrosamine impurity issue?
22 A. I would -- I assume that
23 that communication went as far as the
24 recall process.

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1 Q. And are you familiar with
2 the details of how Teva identifies the
3 pharmacies to receive those notices and
4 how they are sent, or is that someone
5 else?
6 A. That would be someone else
7 in terms of the specifics.
8 Q. Generally, you understand
9 that usually does and did happen here, to
10 some extent, right?
11 A. That is correct.
12 Q. You're just not prepared to
13 testify today about the specifics and
14 detail of how Teva identified the
15 pharmacies to receive notification,
16 specifically when and how they received
17 the notification, fair?
18 A. That is correct.
19 And there is a process we
20 have -- a process for the recall
21 activities where we have a company that's
22 called Inmar.
23 And Inmar is the one that
24 manages these recalls. They are the ones

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1 that have their own processes as to who
2 to send these notifications to.
3 Q. To your knowledge, did Teva
4 ever disclose to its U.S. customers,
5 prior to July 3rd, 2018, that any of
6 Teva's finished-dose valsartan products
7 might contain nitrosamine impurities?
8 A. I would -- I would doubt
9 that.
10 Q. To your knowledge, did Teva
11 ever disclose to its customers that some
12 of the valsartan API that Teva sourced
13 for its finished-dose valsartan might
14 have contained nitrosamine impurities?
15 MS. LOCKARD: Don't
16 speculate.
17 THE WITNESS: I think the --
18 counsel, could you be more
19 specific on your question, please?
20 BY MR. STANOCH:
21 Q. Sure.
22 Prior to July 3rd, 2018, did
23 Teva ever disclose to its U.S. customers
24 that valsartan API that Teva was sourcing

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1 for finished-dose valsartan might contain
2 nitrosamine impurities?
3 A. Based on the process that we
4 have, I don't see how we could have
5 communicated something that we were still
6 trying to assess.
7 Q. Prior to July 3rd, 2018, did
8 Teva ever disclose to its U.S. customers
9 that valsartan API used in Teva's
10 valsartan finished dose was manufactured
11 using recovered solvents?
12 A. We had no information prior
13 to that date that would lead us to make
14 that type of conclusion --
15 Q. Do you know --
16 A. -- or statement.
17 Q. Prior to July 3rd, 2018, did
18 Teva ever disclose to any U.S. retail
19 pharmacy or consumer that Teva's
20 valsartan finished-dose products might
21 contain nitrosamine impurities?
22 A. No, because we didn't have
23 information to that effect to communicate
24 to those customers.

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1 Q. Prior to July 3rd, 2018, to
2 your knowledge, did Teva ever disclose to
3 any U.S. retail pharmacies or consumers
4 that valsartan API that Teva was sourcing
5 for its finished-dose valsartan might
6 contain nitrosamine impurities?
7 A. It is the same response.
8 It's a no.
9 Q. Prior to July 3rd, 2018, did
10 Teva ever disclose to any U.S. retail
11 pharmacies or consumers that valsartan
12 API Teva was sourcing for its
13 finished-dose valsartan was manufactured
14 using recovered solvents?
15 A. No.
16 Q. To your knowledge, do
17 nitrosamines appear on the FDA approved
18 labels for any of Teva's finished-dose
19 valsartan products?
20 A. You mean today?
21 Q. First, today, yes.
22 A. I don't work for the
23 organization at this point, so I think
24 that's a question that Binsol should be

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1 in a better position to answer.
2 Q. Did -- strike that.
3 Do nitrosamines appear --
4 strike that.
5 Do nitrosamines appear on
6 the FDA-approved labels for any Teva
7 finished-dose products that you know of,
8 regardless of time period?
9 A. No.
10 Q. Prior to July 3rd, 2018, did
11 nitrosamines appear on any FDA-approved
12 label for Teva's finished-dose valsartan
13 products?
14 A. No.
15 Q. To your knowledge, did Teva
16 represent to U.S. customers, prior to
17 July 3rd, 2018, that all of its valsartan
18 finished-dose product had met the purity
19 and quality characteristics which the
20 product purported to have?
21 A. Yes.
22 Q. Prior to July 3rd, 2018, did
23 Teva represent to U.S. retail pharmacies
24 and consumers that all of Teva's

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1 valsartan finished-dose product had met
2 the purity and quality characteristics
3 the product was purported to have?
4 A. Through its labeling and
5 through its availability, yes.
6 Q. We -- I'll ask the question
7 first.
8 Are you aware of any
9 communications from any wholesaler or
10 retail pharmacy asking Teva for copies of
11 any testing results concerning Teva's
12 finished-dose valsartan or the valsartan
13 API used to make it?
14 A. You mean today or at the
15 time?
16 Q. Ever.
17 A. Well, today, I don't know,
18 because I am not a part of Teva.
19 There may have been a
20 question, but I am -- I am not certain to
21 say yes or no.
22 Q. Is it fair to say you're not
23 prepared to testify today, on behalf of
24 Teva, about any specific requests from

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1 wholesalers or U.S. pharmacies for
2 testing results, audits, regulatory
3 agency findings relating to finished-dose
4 valsartan or valsartan API?
5 A. That would be correct.
6 MS. LOCKARD: And, again, as
7 we've said, Teva has designated
8 another witness to cover those
9 communications.
10 MR. STANOCH: Thank you,
11 counsel.
12 BY MR. STANOCH:
13 Q. Mr. Barreto, I believe you
14 testified there was a third party that
15 worked with Teva to implement the recalls
16 of Teva's finished dose in the United
17 States?
18 A. That is correct.
19 Q. Can you just tell me that
20 entity again?
21 A. The name of the company is
22 Inmar, I-N-M-A-R, if I spelled it
23 correctly.
24 Q. And can you tell me the

Page 603

1 details of how the recall of Teva's
2 finished-dose valsartan product in the
3 U.S. worked?
4 A. So the process is that once
5 we decide that a recall is going to be
6 implemented, the first thing that we do
7 is we contact the U.S. Food and Drug
8 Administration to let them know of our
9 decision to recall.
10 There is a communication
11 between -- a number of communications
12 between the FDA and us with respect to,
13 for instance, the content of the recall
14 letter and potentially about, you know,
15 other types of communication.
16 Once this is approved, the
17 Teva group then gives the go-ahead to
18 Inmar to then proceed with the process of
19 implementing the recall.
20 Q. And you're aware that Teva
21 had provided the FDA regular written
22 reports concerning the status of Teva's
23 recall efforts?
24 A. Yes, I am aware.

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1 Q. Did you have any involvement
2 in the preparation of those reports to
3 the FDA?
4 A. Yes.
5 Q. You did. Okay.
6 Tell me what your --
7 A. So there were several times
8 when, you know, there were discussions as
9 to the extent to which -- you know, the
10 communication that was being prepared to
11 be sent to the FDA fulfilled, you know,
12 our external expectations on clarity, you
13 know, detailed description of the
14 discussions. Yep.
15 Q. Did you have
16 responsibilities for identifying the
17 logistical data for the drug product that
18 was being sequestered and held?
19 A. There is a group within the
20 quality organization that does that.
21 Q. So it sounds like you were
22 involved in, maybe, the communications to
23 the FDA about Teva's recall process, but
24 you weren't involved in the underlying

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1 detail of identifying the status of all
2 the product, where it is, where it's
3 going, et cetera?
4 A. In general, I was aware.
5 But the detailed part is handled by
6 another group.
7 Q. One moment, please.
8 A. Yes.
9 Q. Who was it in the Teva other
10 group, as you mentioned, who was
11 responsible for the detail for the recall
12 data?
13 A. So for, you know, like,
14 daily activities and the details, David
15 Bonilla is one of these individuals and
16 the other is Constance Truemper.
17 MR. STANOCH: I don't have
18 the prior exhibit, so I'll mark it
19 for now as Teva-175 and change it
20 later.
21 - - -
22 (Whereupon, Exhibit
23 Teva-175,
24 TEVA-MDL2875-00065014-5016,

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1 8/20/18 Letter, Truemper to
2 Herber, was marked for
3 identification.)
4 - - -
5 MR. STANOCH: Sir, that's
6 Bates ending 65014.
7 THE WITNESS: I'm opening
8 it.
9 Yes, sir.
10 BY MR. STANOCH:
11 Q. You're familiar with this
12 document?
13 A. Yes, I am.
14 Q. And this appears to be an
15 August 20, 2018, letter from Ms. Connie
16 Truemper, at Teva, to the FDA.
17 And it says it's a first
18 monthly status report on the voluntary
19 recall of valsartan product; is that
20 right?
21 A. That is correct.
22 Q. And this was the first such
23 report that you're aware of, I assume?
24 A. This would be the first

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1 update, yes.
2 Q. And were you involved in the
3 preparation of this letter to the FDA?
4 A. I may have looked at it.
5 But this is something that she would --
6 she would have prepared herself. I may
7 just have been copied on it.
8 Q. And the second and third
9 pages is data of recall status.
10 Do you know how any of this
11 information was put together for these
12 two pages?
13 A. So this would be information
14 that would be, again, collected from
15 interaction between Ms. Truemper and
16 Inmar.
17 Q. Got it.
18 You're not familiar with the
19 detail of how the data reflected in these
20 two pages appended to the letter to the
21 FDA, how they were generated; is that
22 fair?
23 A. No, no. That's fair.
24 Q. In the cover of the letter

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1 it mentions that the return stocks were
2 being handled by the third-party vendor
3 Inmar, right? You see that in the second
4 paragraph?
5 A. Correct. I do.
6 Q. That was the vendor you
7 mentioned before, right?
8 A. That's correct.
9 Q. And it says, Teva
10 Pharmaceuticals, USA, Inc., will ensure
11 destruction of these returned goods via
12 incineration.
13 Do you see that?
14 A. I see that.
15 Q. So in August 2018, Teva was
16 telling the FDA that it was going to
17 destroy returned valsartan finished-dose
18 product via incineration, correct?
19 A. That is correct.
20 Q. That was Teva's standard
21 process, was it not, to destroy returned
22 product that had been recalled?
23 A. Under routine, you know,
24 recall conditions, this is what we would

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1 do. But in this case, those lots were
2 not destroyed.
3 Q. How do you know lots -- no
4 lots of valsartan finished-dose product
5 was destroyed?
6 A. We put a hold, as a company,
7 on -- at the advice of counsel not to
8 destroy them.
9 So at the time this was
10 written, that was the, again, like, the
11 routine language. Nevertheless, I have
12 confirmed that no destruction
13 certificates have been generated and that
14 every single lot of valsartan, it is --
15 it is still on hold.
16 Q. That's finished-dose
17 valsartan product for the United States
18 market, right?
19 A. That is correct.
20 Q. And when did Teva put a hold
21 on the destruction of recalled valsartan
22 finished-dose product?
23 A. That was -- I want to say
24 that was just right around the -- maybe

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1 two weeks, maybe, a couple of weeks
2 before, you know, we started the process
3 of initiating the recall.
4 So that was a legal hold,
5 and that legal hold was communicated to
6 the entire company.
7 Q. You're --
8 A. I'm -- and I'm guesstimating
9 the date. I don't have the document in
10 front of me.
11 Q. Why don't -- I don't have it
12 either.
13 So if you can tell me more
14 detail in terms of timing, maybe by
15 reference to other events we've
16 discussed.
17 What's your best guess as to
18 when that legal hold went into effect?
19 A. I would have to get that
20 information for you. I don't -- don't
21 have it with me right now. So my
22 apologies.
23 Q. You agree that this exhibit
24 we're looking at here, this August 20th,

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1 2018, letter to the FDA from Teva makes
2 no mention of a legal hold on the
3 destruction of finished-dose valsartan,
4 yes?
5 A. That is correct.
6 But, again, with respect to
7 the timing, I don't recall now if it was
8 before or after.
9 But the hold that was placed
10 to ensure that every lot of valsartan
11 that was recalled from the United States
12 is now on hold, still on hold.
13 Q. And all of those lots are
14 sequestered at an Inmar facility?
15 A. That's my understanding,
16 yes.
17 MR. STANOCH: Here is the
18 next exhibit. Again, it was
19 previously marked, I don't have
20 the number. It's now Teva-176.
21 - - -
22 (Whereupon, Exhibit
23 Teva-176, No Bates, 8/8/19 Letter,
24 Singh to Priester, was marked for

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1 identification.)
2 - - -
3 THE WITNESS: Just let me
4 open it.
5 Yes, sir.
6 BY MR. STANOCH:
7 Q. And this is an August 8th,
8 2019, letter from Teva to the FDA
9 concerning the status of its recall
10 efforts; is that right?
11 A. Yes, that's correct.
12 Q. This one says it's the
13 seventh monthly status report, correct?
14 A. Let me go through it for a
15 second.
16 Q. Sure.
17 A. Yes, that's correct.
18 Q. And this one mentions, in
19 the last paragraph, that Teva initiated a
20 legal hold on destroying ARB drug
21 products that are recalled due to
22 nitrosamine impurities.
23 Do you see that? Last
24 paragraph.

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1 A. I'm looking at it.
2 Yes.
3 Q. And we went over this with
4 Ms. Elizabeth Gray, another Teva
5 designee, that this appeared to be the
6 first of these regular monthly status
7 reports to the FDA that mentioned Teva's
8 legal hold on the valsartan product.
9 Is that consistent with your
10 understanding as well?
11 A. It probably is. I would
12 have to look at the previous monthly
13 updates.
14 But I can assure you, as I
15 indicated before, that that legal hold
16 was present probably around the first
17 time that we said that we needed to do a
18 recall and to preserve -- and to preserve
19 the product.
20 Q. But sitting here today, you
21 can't tell me the date of that legal
22 hold; is that right?
23 A. I would have to -- I want to
24 say -- I can't -- I will not speculate.

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1 Q. That's fair.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 Q. Are you aware of any --
16 MS. LOCKARD: Let me just
17 object to the extent the question
18 calls for speculation. And the
19 decision -- the legal hold was a
20 legal determination. So this is
21 not something that Mr. Barreto was
22 responsible for responding to
23 under the notice.
24 MR. STANOCH: I mean, Topic

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1 48, counsel, is Teva's product
2 recall and the retention of
3 recalled or sequestered valsartan
4 finished dose.
5 So, I mean, if you want to
6 tell me someone else will talk
7 about it, that's fine. But
8 otherwise --
9 MS. LOCKARD: Right. And
10 he's talked about the retention of
11 the medication.
12 But you're asking about the
13 legal hold notice that was issued
14 by the legal department.
15 MR. STANOCH: Which is the
16 basis of the retention or
17 sequestering of the product. And
18 he testified he doesn't know the
19 date of it. So I'm trying to
20 understand who it went to -- the
21 facts of who it went to and when.
22 MS. LOCKARD: Well, he's
23 not -- he's not -- I don't believe
24 that's within the notice, in terms

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1 of recipients of all the
2 litigation hold.
3 And, you know, I object to
4 that as being outside of the
5 scope.
6 MR. STANOCH: Okay. It's
7 noted.
8 BY MR. STANOCH:
9 Q. Mr. Barreto, are you aware
10 of specific communication from Teva to
11 Inmar instructing Inmar not to destroy
12 valsartan finished-dose product that was
13 being recalled because of the nitrosamine
14 impurities?
15 A. I am not specifically aware
16 of that. That would have been Mrs.
17 Truemper.
18 But the legal notice was
19 specific enough to state that the product
20 couldn't be destroyed. So as part of her
21 responsibilities, she would have
22 communicated with them to -- because
23 there is no destruction without Teva's
24 authorization anyway. So it would not

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1 happen unless Teva authorized it.
2 Q. You're not aware of any
3 communication informing Inmar not to
4 destroy the recalled valsartan
5 finished-dose product?
6 A. Not specifically -- not
7 specifically at this moment.
8 But I am speaking about the
9 process of how it works.
10 Q. And do you know why Teva did
11 not inform the FDA that it initiated a
12 legal hold on the destruction of
13 valsartan finished-dose product that was
14 being recalled until August 2019?
15 A. This process is an internal
16 process. And it makes no difference --
17 in terms of, in my opinion, based on my
18 experience, with respect to notification
19 to the FDA.
20 The responsibility with
21 respect to the management of the product
22 resides with Teva. Teva -- it was an
23 issue of timing. Teva eventually
24 notified the FDA. So, to me, that still

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1 fulfills, let's say, an information
2 notice to the FDA.
3 Q. Are you aware of Teva
4 contacting the FDA, at various times,
5 asking or suggesting that -- strike that.
6 Are you aware that Teva
7 contacted the FDA multiple times about
8 destroying recalled valsartan
9 finished-dose product?
10 A. There may have been some
11 communications with respect to that.
12 Again, within the routine process which,
13 obviously, later on, was clarified
14 through the advertisement of the legal
15 hold.
16 Q. For instance, take a look at
17 this next exhibit.
18 MR. STANOCH: Stand by.
19 I'll introduce it here as
20 Teva-177. It's Bates 14826.
21 THE WITNESS: Yes.
22 - - -
23 (Whereupon, Exhibit
24 Teva-177,

Page 619

1 TEVA-MDL2875-00014826-4827, 1/4/19
2 E-mail, Dellarese to Truemper, was
3 marked for identification.)
4 - - -
5 BY MR. STANOCH:
6 Q. And, here, this appears to
7 be an e-mail between Teva personnel and
8 the FDA, right, concerning the
9 destruction of Teva's recalled valsartan
10 product; is that right?
11 A. Yes.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 620

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 Q. Do you know whether or not

Page 621

1 Ms. Truemper ever received a notice of
2 the legal hold on the destruction of
3 valsartan recalled product?
4 MS. LOCKARD: Objection.
5 Outside the scope of his testimony
6 under the notice. Calls for
7 speculation.
8 THE WITNESS: I don't know.
9 MR. STANOCH: I'm going to
10 mark another exhibit, sir.
11 Teva-178. It might have been
12 marked earlier, but this is Bates
13 ending 14763.
14 - - -
15 (Whereupon, Exhibit
16 Teva-178, TEVA-MDL2875-00014763,
17 1/1/19 E-mail, Ora Pharm1 Recalls
18 to Truemper, was marked for
19 identification.)
20 - - -
21 BY MR. STANOCH:
22 Q. Do you have that, sir?
23 A. I do.
24 Q. This is an e-mail chain now

Page 622

1 from March 30th and April 1st of 2019,
2 between Ms. Truemper, and copying a Usha
3 Singh, to the FDA.
4 Do you see that?
5 A. I see that.
6 Q. And Usha Singh, that was
7 another Teva employee, right?
8 A. That is correct.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 623

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 MS. LOCKARD: Objection to
5 form. Asked and answered.
6 THE WITNESS: The reason why
7 I believe she's doing this is
8 because, again, that oversight,
9 for whatever reason, and I cannot
10 speculate on, is still there.
11 The legal hold is still in
12 place. And every lot that was
13 recalled was -- is still on hold.
14 BY MR. STANOCH:
15 Q. And this time Ms. Truemper's
16 message is copied to Usha Singh at Teva,
17 right?
18 A. Yes.
19 Q. And Usha Singh doesn't reply
20 anywhere on the thread to say, hey, we
21 should not destroy it because of the
22 litigation hold; is that right?
23 A. The reason why, I think, is
24 Usha is -- works under Connie at that

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1 point -- I'm sorry, under David, and they
2 are basically colleagues. She was
3 relatively new within the organization.
4 So I think -- this is really
5 about an oversight by the -- this
6 employee. And that's how I characterize
7 it.
8 Q. So now we have two employees
9 at Teva who -- with an oversight not
10 realizing there's a legal hold in place;
11 Ms. Truemper herself, right, as well as
12 Ms. Usha Singh, correct?
13 MS. LOCKARD: Object to the
14 form of the question. It
15 misstates the testimony.
16 There's no indication that
17 these witnesses did not know there
18 was a legal hold in place.
19 MR. STANOCH: You don't need
20 to testify, counsel. He said it
21 was an oversight. I'm asking him
22 to confirm his testimony.
23 Go ahead, Mr. Barreto.
24 THE WITNESS: I still insist

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1 that this is an oversight. I'm
2 not saying that they didn't know,
3 but for whatever reason, you know,
4 they -- they were just following
5 the standard process without
6 really realizing that this was a
7 unique and distinct case.
8 That's what I'm trying to
9 say, counsel.
10 BY MR. STANOCH:
11 Q. Did Teva not have a process
12 in place to suspend the normal process
13 for destruction of recalled product in
14 this instance, given that you believe
15 there was a legal hold in place?
16 A. This is an unusual
17 situation, the one that we are facing.
18 So a process by itself, it's
19 just based on instructions and guidance,
20 and that's how we were working. There
21 was no -- again, the legal -- the
22 objectives of the legal hold remain in
23 place.
24 Q. So you're not aware of any

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1 policy at Teva that would have ensured
2 that employees such as Ms. Truemper and
3 Mr. Singh received notification not to
4 destroy recalled valsartan product,
5 correct?
6 MS. LOCKARD: Objection to
7 the form of the question. I think
8 you're getting outside the bounds
9 of the notice. And you're asking
10 him about policies with respect to
11 issuing legal holds, which is not
12 in his department.
13 MR. STANOCH: Go ahead, sir,
14 you can answer.
15 THE WITNESS: So the legal
16 hold was given to everybody who
17 needed to know about it. And that
18 is the process that was in place.
19 And, again, as I indicated
20 to you, this is a very unusual,
21 very evolving situation. So the
22 best way that I can characterize
23 what Ms. Truemper was doing, she
24 was trying to sort of follow the

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1 administrative steps that are also
2 with every recall, as an
3 oversight, without realizing that
4 that's not what was expected for
5 this case.
6 The reason I am very
7 comfortable about this is the fact
8 that the objectives of the legal
9 hold have been maintained from day
10 one.
11 BY MR. STANOCH:
12 Q. That's based on your belief
13 that no valsartan finished dose was
14 destroyed in the U.S., right?
15 A. That's based on my
16 knowledge.
17 Q. Right. Right. So you're
18 saying no harm, no foul, Ms. Truemper and
19 Ms. Singh, they might have been trying to
20 get it destroyed, but it didn't happen
21 anyway, so no big deal?
22 MS. LOCKARD: Objection to
23 the form of the question. It's
24 argumentative. No one said

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1 anything about harm or foul or
2 that they were trying to get it
3 destroyed.
4 BY MR. STANOCH:
5 Q. Well, how would you
6 characterize the e-mails from Ms.
7 Truemper to the FDA where she's asking if
8 Teva can destroy the recalled valsartan
9 products, Mr. Barreto?
10 A. The way that I would
11 characterize it is she was trying to
12 follow procedure, without really
13 realizing that, in this specific case,
14 that procedure was not totally
15 applicable.
16 Q. Right. And what procedure
17 at Teva --
18 MS. LOCKARD: Objection.
19 MR. STANOCH: Go ahead. I'm
20 sorry.
21 MS. LOCKARD: Objection to
22 the question calling for
23 speculation. Don't speculate
24 about what Ms. Truemper thought or

<p style="text-align: right;">Page 629</p> <p>1 assumed.</p> <p>2 MR. STANOCH: Are you done</p> <p>3 coaching the witness, counsel?</p> <p>4 MS. LOCKARD: No, I'm done</p> <p>5 making my objection. Are you done</p> <p>6 arguing and badgering him about</p> <p>7 somebody else's e-mail?</p> <p>8 MR. STANOCH: I strongly --</p> <p>9 strongly disagree and resent that</p> <p>10 accusation, counsel. He's</p> <p>11 designated on the Topic 48, on the</p> <p>12 retention and sequestering of</p> <p>13 valsartan finished-dose products.</p> <p>14 There's an e-mail talking</p> <p>15 here, of Teva, about the</p> <p>16 destruction of those products.</p> <p>17 I'm going to keep asking him the</p> <p>18 questions. I think it's within</p> <p>19 the scope of the notice.</p> <p>20 MS. LOCKARD: Let's take a</p> <p>21 break, then. You can continue</p> <p>22 after the break.</p> <p>23 VIDEO TECHNICIAN: The time</p> <p>24 is now 1:59 p.m. Going off the</p>	<p style="text-align: right;">Page 631</p> <p>1 I'm asking you, you know --</p> <p>2 MS. LOCKARD: No, we're not.</p> <p>3 The record is still going. I'm</p> <p>4 watching --</p> <p>5 COURT REPORTER: That's</p> <p>6 because I wasn't sure what you</p> <p>7 wanted me to do. Because I heard</p> <p>8 David say, I don't want to go off,</p> <p>9 and she went off.</p> <p>10 MR. STANOCH: Let's go off</p> <p>11 the record now.</p> <p>12 - - -</p> <p>13 (Whereupon, a brief recess</p> <p>14 was taken.)</p> <p>15 - - -</p> <p>16 VIDEO TECHNICIAN: The time</p> <p>17 is now 2:06 p.m. Back on the</p> <p>18 record.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Mr. Barreto, in preparation</p> <p>21 for today's deposition, did you speak to</p> <p>22 Ms. Connie Truemper?</p> <p>23 A. No.</p> <p>24 Q. In preparation for today's</p>
<p style="text-align: right;">Page 630</p> <p>1 record.</p> <p>2 MR. STANOCH: I didn't agree</p> <p>3 to that break, by the way,</p> <p>4 Victoria.</p> <p>5 I don't understand -- if</p> <p>6 you're going to have someone -- I</p> <p>7 asked you at the beginning of</p> <p>8 this, if you're going to have</p> <p>9 somebody else talk about this,</p> <p>10 great. And you said, no, he's</p> <p>11 ready to talk about it.</p> <p>12 So I'm asking him. And then</p> <p>13 when you don't like a question,</p> <p>14 you say it's outside the scope and</p> <p>15 it's speculative and he doesn't</p> <p>16 know and why are you asking him,</p> <p>17 you should ask Constance.</p> <p>18 What do you want me to do?</p> <p>19 MS. LOCKARD: I've asked for</p> <p>20 a break. I'd like to go off the</p> <p>21 record for a moment.</p> <p>22 MR. STANOCH: Well, we're</p> <p>23 off already. We already got that.</p> <p>24 You got your break.</p>	<p style="text-align: right;">Page 632</p> <p>1 deposition, did you speak to Usha Singh?</p> <p>2 A. No.</p> <p>3 Q. So you really can't testify</p> <p>4 as to why they were telling the FDA -- or</p> <p>5 asking the FDA for permission to destroy</p> <p>6 valsartan product that had been recalled,</p> <p>7 because you didn't talk to them; is that</p> <p>8 fair?</p> <p>9 A. But I did speak with Mr.</p> <p>10 Bonilla.</p> <p>11 Q. You did?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Okay. When did you talk to</p> <p>14 Mr. Bonilla?</p> <p>15 A. It must have been a few days</p> <p>16 ago.</p> <p>17 Q. And what did you talk about</p> <p>18 with Mr. Bonilla?</p> <p>19 MS. LOCKARD: Was counsel</p> <p>20 present?</p> <p>21 THE WITNESS: That was with</p> <p>22 counsel present.</p> <p>23 It was -- it was to ensure</p> <p>24 that we could confirm that the</p>

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1 instructions that were set for the
2 legal hold had been not only
3 implemented but that they had been
4 communicated to Inmar.
5 BY MR. STANOCH:
6 Q. Is the sole basis for your
7 testimony today about whether recalled
8 valsartan product was destroyed or not
9 based on information you received from
10 Mr. David Bonilla?
11 A. Based on the confirmation
12 that I received from Mr. Bonilla, yes.
13 Q. One moment, please.
14 Did anyone else, other than
15 counsel, provide you any information to
16 inform you about whether valsartan
17 product recalled in the United States was
18 destroyed?
19 A. What's the question?
20 Q. Did anyone else, other than
21 your counsel or Mr. Bonilla, provide you
22 information about whether or not recalled
23 valsartan product was destroyed or not?
24 A. No.

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1 Q. And earlier I believe you
2 said that there is no certificates of
3 destruction issued in connection with
4 valsartan product that had been recalled;
5 is that right?
6 A. That is correct.
7 Q. And what's a certificate of
8 destruction?
9 A. A -- once the product is
10 destroyed, a certificate of destruction
11 is generated to document that that
12 article is no longer in existence and
13 it's been destroyed.
14 Q. Did you review any records
15 regarding whether or not valsartan
16 recalled product was destroyed?
17 A. There would be --
18 MS. LOCKARD: Objection to
19 the form of the question. It's
20 confusing, because you're asking
21 him about documents that don't
22 exist.
23 He can explain.
24 THE WITNESS: And that's

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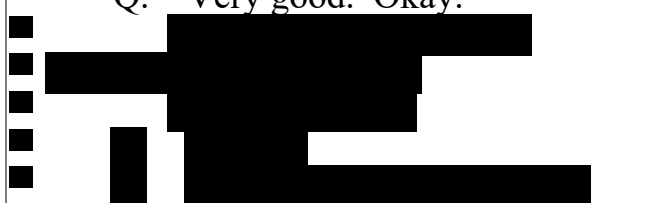
1 exactly what I was going to say,
2 that I have not reviewed any
3 certificate of destruction because
4 none exists and there's nothing to
5 review.
6 BY MR. STANOCH:
7 Q. In preparation for your
8 deposition today, did you undertake to
9 investigate whether any certificates of
10 destruction exist for valsartan
11 finished-dose product?
12 A. That was part of the
13 discussion we had with Mr. Bonilla.
14 MR. STANOCH: I'm going to
15 mark the next exhibit. Did that
16 go through or not? I'll try it
17 again.
18 THE WITNESS: What's the
19 number, counsel?
20 MR. STANOCH: Teva-179, sir.
21 - - -
22 (Whereupon, Exhibit
23 Teva-179,
24 TEVA-MDL2875-00717000-7014,

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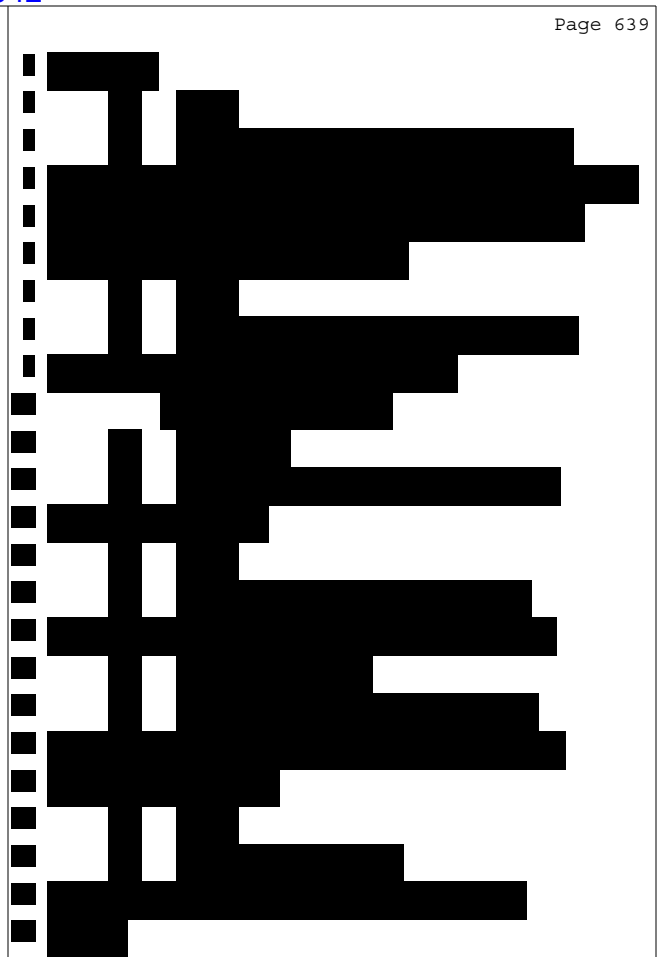
1 11/27/19 E-mail, Singh to Nase,
2 was marked for identification.)
3 - - -
4 MS. LOCKARD: 179.
5 THE WITNESS: Yes, sir.
6 BY MR. STANOCH:
7 Q. What's the -- what's the
8 Bates number you see on the first page
9 there, sir?
10 A. What's the question?
11 Q. What's the Bates number in
12 the lower right on the first page you
13 see, sir?
14 I'm just making sure I'm
15 looking at the same thing as you.
16 A. This is an e-mail from --
17 it's 11/27/2019, 6:45:10 p.m.
18 Q. Got it.
19 Have you seen this before?
20 A. No.
21 Q. So let's scroll to the
22 attachments here, if you will.
23 A. Yes, sir.
24 Q. And I can share my screen if

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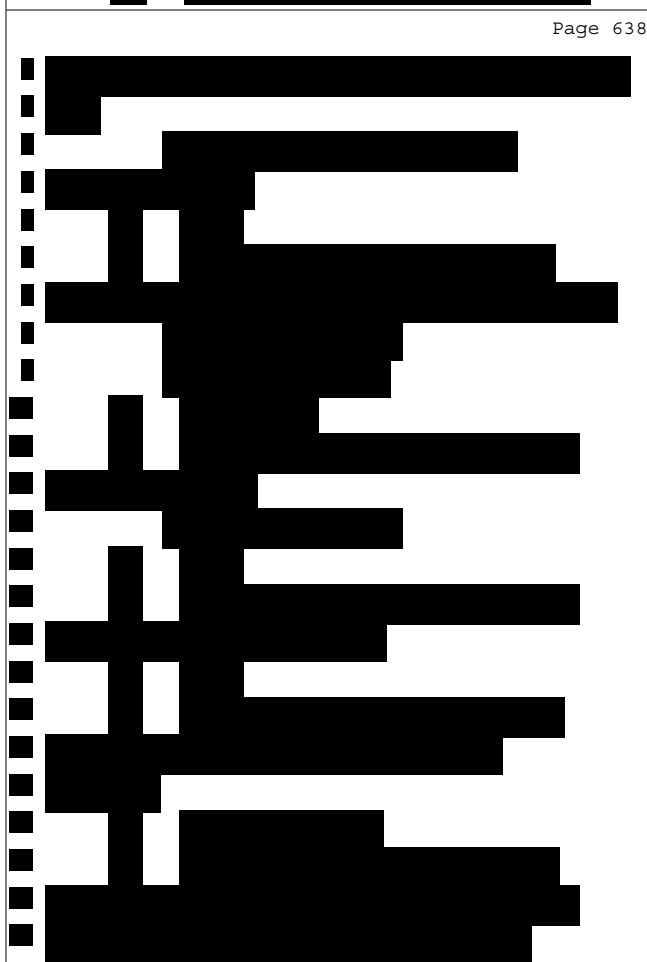
1 necessary.
2 But I'm going to -- I'll
3 share my screen, I think it will move it
4 along for you, sir. Give me one second.
5 Okay. Go to this page,
6 please, bearing Bates 717006.
7 A. Unfortunately, I'm looking
8 at it sideways, so it's very difficult
9 for me to --
10 Q. I know, I have the same
11 issue. Let me see if I can rotate it for
12 you. No.
13 A. I tried that yesterday,
14 counsel.
15 Q. I know, I remember, sir.
16 Here we go.
17 Is this better for you?
18 A. Yes, sir.
19 Q. Very good. Okay.



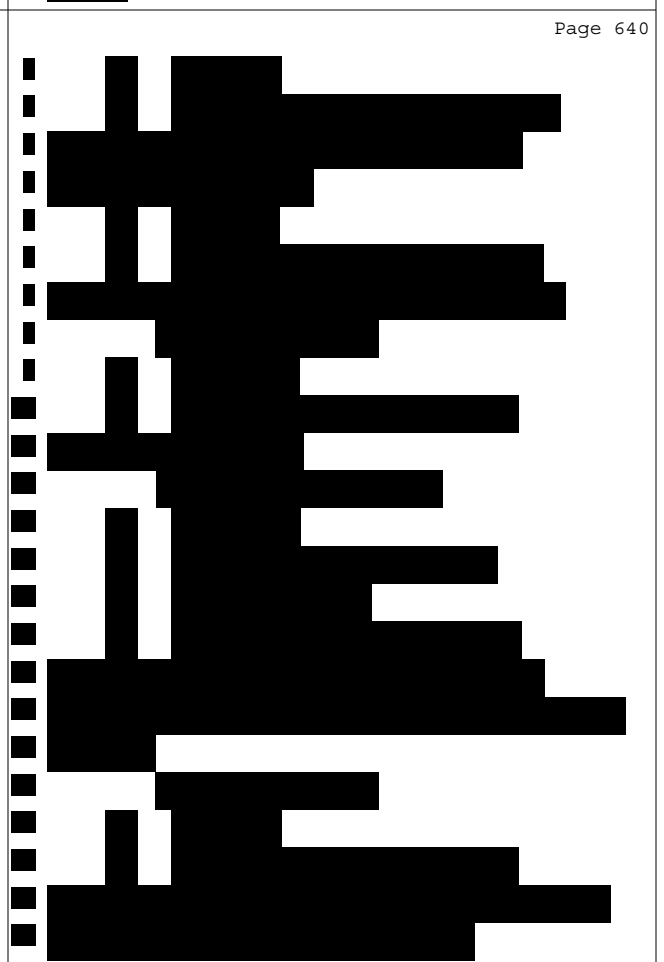
Page 639



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Page 641

[REDACTED]

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1 distribution center that was not
2 distributed to customers within the
3 United States versus the product that was
4 recalled that was actually retrieved and
5 placed on hold.
6 So I think that is the
7 difference that maybe we need to discuss
8 in this case.
9 Q. Well, so the distinction
10 you're making is that -- is, what, that
11 this specific valsartan product in the
12 U.S. that was destroyed was not recalled,
13 therefore, it was not subject to the
14 litigation hold?
15 A. That this is not part of the
16 material that was retrieved from the
17 distribution -- the distribution chain
18 versus material that was placed on hold
19 which was not distributed.
20 Q. So because the material had
21 not been returned to Teva from a
22 customer, Teva had it on hand, it was
23 okay for Teva to destroy it, you think?
24 A. I have to look at what the

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[REDACTED]

18 Q. And you agree that that's
19 several months after the nitrosamine
20 issues were brought to Teva's attention
21 in late June or early July of 2018,
22 correct?
23 A. Except that I think that you
24 are talking about product that was in our

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1 specifics of the hold were to ensure
2 that. I need to look at the specifics to
3 give you an answer.
4 Q. I don't have the hold
5 because it wasn't produced to me.
6 So, Mr. Barreto, is -- Mr.
7 Barreto, is there anything you can tell
8 me about the litigation hold, about
9 whether it applied to only recalled
10 finished-dose valsartan product that was
11 returned by a customer, a third party, to
12 Teva, or if it also included
13 finished-dose valsartan product that Teva
14 also had on hand in its own inventory at
15 the time?
16 MS. LOCKARD: I'm just going
17 to object to the extent that
18 you're getting into the legal hold
19 notice. And I think that's a
20 legal question as to how it should
21 be interpreted.
22 I'm not sure he's the right
23 person to answer that particular
24 question.

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1 MR. STANOCH: You can
2 answer, sir.
3 THE WITNESS: I would have
4 to look at the legal hold to see
5 the extent to which I could answer
6 the question.
7 Because the legal hold -- I
8 have to look at that specific
9 request with respect to product.
10 And I don't have it in front of me
11 right now, counsel.
12 MR. STANOCH: Counsel, we're
13 going to request the legal hold,
14 because the witness says he can't
15 testify about the details of the
16 retention and potential
17 destruction of the product, per
18 Topic 48, without the legal hold.
19 MS. LOCKARD: No, that's not
20 what the witness said. And we can
21 address this off the record for
22 this witness.
23 But I disagree that that's
24 what he said. He testified to

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1 you -- he's testified he's done
2 the investigation, he's spoken
3 with the right people, he's looked
4 through the documents. And so
5 he's prepared on the topic.
6 BY MR. STANOCH:
7 Q. Mr. Barreto, can you --
8 MR. STANOCH: Ms. Lockard, I
9 disagree, we're requesting any
10 holds that were in place for
11 valsartan product, number one.
12 BY MR. STANOCH:
13 Q. Number two, Mr. Barreto, can
14 you tell me, sitting here today, whether
15 Teva issued any legal hold that covered
16 valsartan finished-dose product in the
17 U.S. that was already in Teva's
18 possession at the time it instituted the
19 recalls?
20 MS. LOCKARD: Objection.
21 Asked and answered.
22 THE WITNESS: The best
23 recollection that I have is that
24 any product that was returned from

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1 distribution needed to be the
2 subject of the legal hold. That
3 is the responsibility for which we
4 implemented the assurance that
5 that was the case. And this is
6 where we placed a focus.
7 I don't know if there was
8 any -- I don't recall if there was
9 any specific guidance with respect
10 to product that was not
11 distributed.
12 But everything that the
13 legal hold said that needed to be
14 recalled -- sorry, to -- withheld
15 from material that was recalled,
16 all of that material is on hold.
17 BY MR. STANOCH:
18 Q. Can you tell me, sitting
19 here today, whether Teva ever issued a
20 legal hold on valsartan finished product
21 in the U.S. that Teva had in its own
22 possession at the time of the recalls?
23 A. I don't recall.
24 Q. Okay. And how would you

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1 refresh your memory as to whether or not
2 that was the case or not?
3 A. As I indicated, I would
4 probably need to take a look at the legal
5 hold and verify that section with respect
6 to product on hold.
7 Q. Did Teva's legal hold extend
8 to valsartan API that was used to produce
9 Teva's valsartan finished-dose product
10 sold in the United States?
11 A. The legal hold, as I recall,
12 it applied to product that was
13 distributed and that was returned.
14 I do not think that there
15 was any discussion about API.
16 Q. So you're not aware of
17 whether or not Teva ever put a hold on
18 valsartan API it had at one of its
19 manufacturing facilities that made
20 valsartan finished dose for the U.S.,
21 right?
22 A. I'd like to clarify.
23 There is a distinction
24 between putting a hold -- and I'm aware

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1 that holds were placed -- versus
2 destruction. And there is a distinction
3 between a legal hold and a routine hold.
4 API that was considered to
5 be unacceptable was placed on hold, and
6 that API is not in Inmar's location
7 because that's not the product that was
8 subject to the recall and the legal hold
9 that was placed by the legal department.
10 Q. So valsartan API that was
11 at, say, the Malta facility, which was
12 intended to be used for U.S.
13 finished-dose product, that was not
14 subject to a legal hold?
15 A. I cannot conclusively state
16 that it was not. But if you ask me for
17 my professional opinion, the answer would
18 be that I suspect that it was not placed
19 on legal hold.
20 Q. And, similarly, do you know
21 whether or not a legal hold was placed on
22 valsartan API that was on site at Teva's
23 Jerusalem facility that manufactured
24 valsartan finished-dose product for the

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1 U.S.?
2 A. The procedures that were
3 implemented were to hold and eventually
4 to dispose of that material. I don't
5 recall that there was a legal hold
6 necessary for those -- that type of
7 product.
8 MS. LOCKARD: I don't want
9 you to speculate. And if we need
10 to take a break to run this down,
11 I'm happy to do that. This is not
12 a memory contest.
13 If you're going to be
14 designated on the topic, I want to
15 make sure you have the information
16 you need.
17 THE WITNESS: Yes. Because
18 I am -- I am speculating at this
19 time, no question about it.
20 BY MR. STANOCH:
21 Q. So do you know whether any
22 valsartan API was destroyed from any Teva
23 facility after July 3rd, 2018?
24 A. I don't have that

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1 information. So I don't know.
2 Q. Did you look into that to
3 prepare for today's deposition?
4 A. No.
5 MR. STANOCH: I'm going to
6 mark the next exhibit, Teva-180.
7 - - -
8 (Whereupon, Exhibit
9 Teva-180,
10 TEVA-MDL2875-00071287-1303,
11 9/29/19 E-mail, Etzioni to Fluch,
12 was marked for identification.)
13 - - -
14 BY MR. STANOCH:
15 Q. Tell me when you're there,
16 sir.
17 A. Yes. One moment.
18 Yes.
19 Q. This is an e-mail chain
20 between multiple Teva employees,
21 including Dana Etzioni, Joerg Fluch, Jens
22 Nassall and Dalia Reuven, topmost message
23 dated September 29th, 2019, correct?
24 A. Yes.

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1 Q. And if you flip to the
2 original message in the thread, it's
3 actually from someone at Mylan to the
4 Teva folks that I just named; is that
5 right?
6 A. Yes.
7 Q. And it's talking about Mylan
8 is -- Mylan was supplying valsartan API
9 to the Teva Jerusalem facility, correct?
10 A. Yes.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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1 Q. Right. Well, first of all,
2 we established yesterday, we can't find
3 an agreement between Teva Jerusalem and
4 Mylan, so we don't know if there was an
5 agreement that covered this situation,
6 right?
7 A. I'm sure there is an
8 understanding in the supply agreement
9 between Teva -- with respect to the
10 return of product. There is an
11 agreement.
12 Q. Well, you testified
13 yesterday that you could not locate a
14 quality technical agreement?
15 A. But I'm saying that there's
16 a difference between a technical
17 agreement and a supply agreement.
18 Q. Understood. I appreciate
19 that distinction.
20 Did you see a supply
21 agreement between Teva and Mylan in
22 preparation for today's deposition?
23 A. No, I did not.
24 Q. Are you aware of any such

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[REDACTED]

6 Q. And then a little --
7 A. And that's not something
8 that would be considered abnormal.
9 There are -- in this case --
10 I'm sure that there were different
11 reasons. So long as the product was
12 classified as being rejected and it was
13 secured in the warehouse, the timing for
14 the destruction is more a case where --
15 you know, in this case, there was no
16 specific reason for the timing other than
17 it was held, perhaps, even for further
18 investigation, number one; number two,
19 you still have to have that agreement
20 with the supplier as to how that API is
21 going to be disposed of; is it going to
22 be returned, is it going to be destroyed,
23 and all of this requires a lot of
24 activities.

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1 one outside of this deposition?
2 A. I'm sure there is a supply
3 agreement in place.
4 Q. Have you seen it?
5 A. No, sir.
6 Q. Has anyone ever told you
7 affirmatively, we have one with them in
8 place?
9 A. No. Again, I'm speculating.
10 But it is customary to have this type of
11 agreement between two companies.
12 Q. And I'm flipping to the page
13 ending 1297. Mr. Etzioni, at Teva,
14 writes that the total quantity is 16 MT.
15 Do you see that?
16 A. Just one second. I have to
17 go back to the document. My apologies.
18 Yes.
19 Q. Actually, hold that page.
20 Before we get to it, you
21 said you thought there was no good reason
22 to hold this rejected Mylan valsartan
23 API.
24 Well, isn't one reason to

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1 test that valsartan API to determine the
2 concentrations of nitrosamines in it?
3 A. In the process of -- to
4 receive these samples, there are samples
5 that are -- these products, there are
6 samples that are maintained.
7 So whether testing is
8 needed, there's always samples that are
9 available for that type of testing.
10 Q. Well, I can't test product
11 that's been destroyed; is that fair?
12 A. You can test samples of
13 product that has been destroyed.
14 Q. If samples exist?
15 A. It is part of the procedure
16 that research samples are maintained of
17 product that is received.
18 Q. Right. And I'm sure in your
19 preparation you saw a number of e-mails
20 regarding the availability or
21 nonavailability of samples of various
22 valsartan API, right?
23 A. I'm sorry, repeat the
24 question.

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1 Q. I'm sure in your preparation
2 for today's deposition you saw, as I
3 have, various e-mails expressing concern
4 within Teva about the availability or
5 nonavailability of valsartan API samples
6 for testing?
7 A. That would be more in terms
8 of availability at specific locations and
9 making sure that samples from other
10 locations are -- so this is more of a
11 logistical issue rather than availability
12 of samples themselves.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

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[REDACTED]

7 Q. And, again, then there's
8 another bunch of these e-mails that go on
9 throughout July, right?
10 Again, you haven't seen any
11 mention so far of any legal hold, do you?
12 A. Again, in this case, as I
13 recall, the expectation of the legal
14 hold, any material that was received from
15 the market through the recall process is
16 the material that needed to be preserved.
17 That's the -- my understanding.
18 If there were other
19 requirements, I would have to double
20 check that at this point. And I don't
21 have access to that document.
22 Q. And then let's flip to the
23 page ending 292. Tell me when you're
24 there.

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1 A. What date would that be,
2 counsel?
3 Q. August 20th, 2019, from Dana
4 Etzioni. It's at the bottom of page
5 ending 292, sir.
6 A. I've got it here, yes.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 MS. LOCKARD: Objection.
24 Misstates the document.

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1 BY MR. STANOCH:
2 Q. And this is approximately a
3 year now after the first status report we
4 saw Teva sent to the FDA in August 2018
5 about its recall efforts in the U.S.
6 market, correct?
7 MS. LOCKARD: Objection.
8 Asked and answered.
9 THE WITNESS: So I have
10 indicated to you, in my opinion,
11 these are -- now we are discussing
12 two distinct processes.
13 As I said to you before, the
14 legal hold is intended to ensure
15 that any recalled product that was
16 retrieved from distribution within
17 the U.S. needed to be placed on
18 the legal hold. That's what we
19 did.
20 BY MR. STANOCH:
21 Q. Is it your testimony that
22 Teva did not issue a legal hold on
23 valsartan API that was used and intended
24 to be sold as part of the finished-dose

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1 valsartan in the U.S. market?
2 MS. LOCKARD: Objection.
3 Calls for speculation based on
4 earlier question and answer.
5 THE WITNESS: It is my
6 statement that what I recall is
7 that the legal hold was intended
8 to ensure that any recalled
9 product that was returned would be
10 preserved.
11 I don't recall if there were
12 specifics, even though I doubt it.
13 But I would need to confirm this
14 by reviewing, once again, the
15 legal hold.
16 BY MR. STANOCH:
17 Q. Understood.
18 If you'd flip, then, to the
19 Page 1291, sir.
20 A. Yes.
21 Q. And the bottom e-mail there
22 is again from Dana Etzioni, dated
23 September 8th, 2019.
24 Do you see that?

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1 A. Yes, sir.
2 Q. And this is to Joerg Fluch,
3 also at Teva, right?
4 A. Yes.
5 Q. And Dana Etzioni --
6 actually, do you know if Dana Etzioni is
7 male or female?
8 A. I don't know.
9 Q. That's fine.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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Q. And if you go a few more pages to page ending 1289, there's another e-mail from Dana Etzioni, September 20th, 2019.

A. And, in my opinion, all of these actions that were taken were proper and correct.

A. I am making a quality

decision for which I'm speaking about processes and procedures within the routine process.

MS. LOCKARD: Objection. That asks for a legal conclusion. You can't argue with him for not being a lawyer and then ask him legal questions.

THE WITNESS: In the course of any investigation, if there is a need for -- so I'm speaking of a

practice rather than a process, because these are decisions that are made on a case-by-case basis.

BY MR. STANOCH:

And from your experience as a quality executive at Teva, are you aware of any policy at Teva that would ensure that normal destruction of rejected API product would be suspended, pending a legal hold, involving the same valsartan API subject to that destruction process?

Again, it's outside the scope of his notice. You're asking him about legal policies with respect to legal hold.

MR. STANOCH: Go ahead, sir.

THE WITNESS: From a quality perspective, it is the practice and the process where, if there is a need to withhold product because we need to do further investigation and further testing on it, that would be a decision that would be made at the discretion of the -- so there is no specific -- this being a case-by-case decision that has to be made, there's no specific instruction that would contemplate every possible scenario where you would -- so this is -- this is one where you apply practice, experience and knowledge.

BY MR. STANOCH:

A. I'm not aware of that.

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1 Q. And, finally, if you look at
2 the first page of this document, sir, the
3 top e-mail from Dana Etzioni, September
4 29th, 2019.
5 She's confirming to other
6 Teva employees that both KFS and JLM have
7 now completed the destruction of
8 material, right?
9 A. That is correct.
10 Q. And JLM is the Teva
11 Jerusalem facility that sourced Mylan
12 valsartan API for finished dose for the
13 U.S. market, right?
14 A. That is correct.
15 Q. And just so we know, KFS,
16 that's another Teva facility in Israel?
17 A. That stands for Kefar Sava
18 in Israel.
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 Q. Do you know if valsartan API
3 sourced from ZHP and Mylan by Teva was
4 destroyed at any other Teva facility
5 besides the two referenced in this
6 exhibit?
7 A. I don't have those details
8 at this moment.
9 Q. Okay. The Teva -- Teva
10 Jerusalem sourcing of the Mylan valsartan
11 API, was it your understanding, from a
12 quality standpoint, that the product
13 should go directly to the Jerusalem
14 facility?
15 A. Can you explain --
16 MS. LOCKARD: Objection.
17 Vague.
18 THE WITNESS: Can you
19 explain your question? I didn't
20 understand it.
21 BY MR. STANOCH:
22 Q. Sure.
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 Q. Okay. Do you know whether
19 or not the valsartan API from Mylan that
20 ended up at Teva's Jerusalem facility
21 ever went to a different Teva facility
22 first?
23 A. I would have to remember the
24 details. But there is a possibility,

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1 yes.
2 Q. You just don't recall that
3 one way or the other?
4 A. I don't recall. But there's
5 a possibility.
6 Q. If that did happen, you
7 would expect that it would be documented
8 in both facilities' paperwork; is that
9 right?
10 A. Absolutely.
11 Q. And that would be required
12 to be kept by GMP?
13 A. Absolutely.
14 Q. Didn't you testify earlier
15 that there was an issue of potential
16 cross-contamination insofar as there was
17 NDMA and NDEA present in Mylan valsartan
18 API?
19 A. I spoke about NDEA.
20 Q. How about NDMA?
21 A. I think that the
22 investigation spoke about some potential
23 cross-contamination. I need to go back,
24 because it's more specific about NDEA

<p style="text-align: right;">Page 673</p> <p>1 than it is about NDMA.</p> <p>2 Q. From a quality perspective,</p> <p>3 would -- wouldn't Teva require API from</p> <p>4 Mylan in order to investigate the extent</p> <p>5 to which the cross-contamination might</p> <p>6 have occurred?</p> <p>7 A. In the course of the</p> <p>8 performance of an investigation, we may</p> <p>9 or may not require it. It all depends</p> <p>10 on -- it's really, again, a case-by-case</p> <p>11 basis.</p> <p>12 If the information generated</p> <p>13 by Mylan was sufficient for us to</p> <p>14 continue with our own investigation, then</p> <p>15 that would be the case.</p> <p>16 Q. So why is it appropriate,</p> <p>17 from a quality standpoint, for Teva to</p> <p>18 incinerate some valsartan API prior to</p> <p>19 fully assessing the extent and nature of</p> <p>20 potential cross-contamination?</p> <p>21 A. Because, as I've stated, at</p> <p>22 that point, there is a conclusion as to</p> <p>23 what the problem is, what the situation</p> <p>24 is, what actions we needed to take.</p>	<p style="text-align: right;">Page 675</p> <p>1 material. So there is sample</p> <p>2 material to test from, even if</p> <p>3 material is destroyed.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. Do you know, one way or the</p> <p>6 other, sitting here today, whether there</p> <p>7 was sufficient samples at Teva's</p> <p>8 Jerusalem facility such that 16 metric</p> <p>9 tons of Mylan valsartan API could be</p> <p>10 destroyed?</p> <p>11 A. The procedures are in place</p> <p>12 at every site for the preservation of</p> <p>13 research samples for every product that</p> <p>14 is received.</p> <p>15 Q. You don't know whether those</p> <p>16 procedures were being followed at Teva</p> <p>17 Jerusalem vis-à-vis the Mylan valsartan</p> <p>18 API, though, do you?</p> <p>19 A. The--</p> <p>20 MS. LOCKARD: Objection.</p> <p>21 Form. Speculation.</p> <p>22 THE WITNESS: The sites are</p> <p>23 responsible for implementing those</p> <p>24 procedures. And our, you know,</p>
<p style="text-align: right;">Page 674</p> <p>1 So in terms of</p> <p>2 investigation, there is a consistent</p> <p>3 amount of information as to what's</p> <p>4 happened and what corrective actions need</p> <p>5 to be taken. So the preservation of that</p> <p>6 material would not necessarily add more</p> <p>7 than what we already know.</p> <p>8 Q. But Jerusalem, we saw,</p> <p>9 destroyed 16 million -- metric tons of</p> <p>10 Mylan valsartan API and there's no</p> <p>11 indication, is there, if that API was</p> <p>12 ever tested; isn't that right?</p> <p>13 MS. LOCKARD: Objection to</p> <p>14 form. It misstates the document.</p> <p>15 Speculation.</p> <p>16 THE WITNESS: Any material</p> <p>17 that was received by Teva was</p> <p>18 tested in accordance with the Teva</p> <p>19 specifications.</p> <p>20 If, in the middle of the</p> <p>21 investigation, samples were</p> <p>22 tested -- I need to go into the</p> <p>23 details. But, as I said, samples</p> <p>24 are preserved of every incoming</p>	<p style="text-align: right;">Page 676</p> <p>1 internal audit programs have not</p> <p>2 revealed any problems with that</p> <p>3 process.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. In preparation for today's</p> <p>6 deposition, did you look into whether</p> <p>7 there was adequate samples of valsartan</p> <p>8 API on hand at Temple's -- Teva's</p> <p>9 Jerusalem facility?</p> <p>10 A. In preparation for this</p> <p>11 discussion, no, I did not look into that.</p> <p>12 Q. Do you know, one way or the</p> <p>13 other, whether there was sufficient</p> <p>14 samples at Teva's Jerusalem facility of</p> <p>15 the 16 metric tons of Mylan valsartan API</p> <p>16 that was destroyed?</p> <p>17 MS. LOCKARD: Objection.</p> <p>18 I'm going to say outside of the</p> <p>19 scope of the notice. We have</p> <p>20 designated someone else on the</p> <p>21 testing issue.</p> <p>22 MR. STANOCH: You can answer</p> <p>23 to your own knowledge if you need</p> <p>24 to.</p>

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1 THE WITNESS: I think Binsol
2 would be in a much better position
3 to tell you exactly what the
4 situation is today.
5 BY MR. STANOCH:
6 Q. You don't know, one way or
7 the other, whether there was sufficient
8 samples at Teva Jerusalem's facility such
9 that 16 metric tons of Mylan valsartan
10 API could be destroyed, right?
11 A. I explained to you that
12 samples that are received are tested,
13 samples are maintained. So those
14 procedures are in place.
15 Q. Right. But you said that
16 you don't know whether or not those
17 procedures were followed at Teva
18 Jerusalem vis-à-vis the Mylan valsartan
19 API, right?
20 A. That's not what I said.
21 That's not what I said.
22 What I said was that our
23 internal audit processes have not
24 indicated that those procedures are not

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1 being followed.
2 Q. And Teva Jerusalem's
3 incoming testing specifications didn't
4 catch the NDMA and NDEA for years, right?
5 A. The analytical test methods
6 that were used at Teva Jerusalem were
7 designed to fulfill the specifications
8 set by the regulators.
9 Q. Can you tell me whether or
10 not there exists adequate samples at Teva
11 Jerusalem of the Mylan valsartan API that
12 Teva incinerated?
13 A. Let me clarify something,
14 that Teva Jerusalem does not -- facility,
15 does not exist anymore.
16 So your question is one that
17 needs to be answered by somebody who now
18 knows where is it that samples and
19 documents and material from the Teva
20 Jerusalem facility are located. So I'm
21 not able to speak about that.
22 Q. That's a fair point, sir.
23 Do you know where any
24 valsartan API samples are today that

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1 might have been at Teva's Jerusalem
2 facility?
3 A. I do not know. I don't work
4 for the company anymore. So they could
5 have been sent to whatever facilities the
6 company decided to send them to.
7 Q. You have no knowledge, one
8 way or the other, about that, right?
9 A. Not -- not today.
10 Q. Right. And you did not look
11 into that to prepare for today's
12 deposition, right?
13 A. I did not. Mr. Binsol would
14 be in a much better position.
15 MS. LOCKARD: Again,
16 objection. This question is
17 outside the scope. The retention
18 of the API is outside of the scope
19 of the notice.
20 And the testing is outside
21 the scope of the notice and what
22 he was designated for.
23 BY MR. STANOCH:
24 Q. And because the Teva

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1 Jerusalem facility no longer exists
2 today, as you stated, you don't know, one
3 way or the other, what the status or
4 sufficiency of any valsartan API samples
5 might have been vis-à-vis the Mylan
6 valsartan API that was incinerated by
7 Teva?
8 A. What I'm stating --
9 MS. LOCKARD: Objection.
10 Vague.
11 THE WITNESS: What I'm
12 stating is that any discussions
13 about where Teva materials in
14 Jerusalem, where -- where they
15 have gone and what sort of process
16 is in place for managing those
17 materials. This is something that
18 is outside of my knowledge at this
19 point.
20 BY MR. STANOCH:
21 Q. You don't know what
22 valsartan API samples were kept at Teva
23 Jerusalem at the time nor which -- nor
24 what samples may exist today, fair?

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1 MS. LOCKARD: Objection.
2 Asked and answered. Outside the
3 scope of the deposition notice for
4 Mr. Barreto.
5 THE WITNESS: I indicated to
6 you that there are procedures in
7 place for the receipt and
8 preservation of samples of
9 products that are received.
10 BY MR. STANOCH:
11 Q. And you have no information,
12 one way or the other, what the samples
13 were that were retained at Teva Jerusalem
14 of valsartan API or where they may be
15 today, correct?
16 MS. LOCKARD: Objection.
17 Asked and answered.
18 THE WITNESS: Today, I have
19 no knowledge of where any
20 materials preserved are located
21 from the former Teva Jerusalem
22 facility.
23 BY MR. STANOCH:
24 Q. Do you know anything about

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1 the number of valsartan API samples that
2 had been kept at Teva Jerusalem prior to
3 its closure?
4 MS. LOCKARD: Objection.
5 Outside the scope of his
6 deposition notice.
7 THE WITNESS: In terms of
8 the expectation, the answer is
9 that the procedures in place call
10 for every lot to -- that is
11 shipped to be -- to be sampled and
12 to be preserved.
13 BY MR. STANOCH:
14 Q. But you didn't look into
15 whether or not those procedures were
16 followed, did you?
17 A. As I have indicated to you,
18 the internal procedures that we have in
19 place do not indicate that those
20 procedures -- the processes for auditing
21 and supervising and monitoring, do not
22 indicate that those procedures have not
23 been followed.
24 Q. If you're going to say

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1 auditing, sir, the audits only happen
2 very periodically, don't they?
3 A. The audit process is not the
4 only way to ascertain whether or not a
5 site is in compliance. There is a
6 concept of, you know, quality assurance
7 organization that does, also, its own
8 internal -- local internal audits. So --
9 and there's quality councils. There's
10 all forms of supervision and monitoring.
11 Q. Sitting here today, can you
12 tell me whether Teva's Jerusalem facility
13 had samples of every Mylan valsartan API
14 lot that was incinerated?
15 MS. LOCKARD: Objection.
16 Outside the scope of this
17 witness's deposition notice.
18 THE WITNESS: As I indicated
19 to you, there are procedures in
20 place that dictate the collection
21 and preservation of samples of
22 APIs received.
23 BY MR. STANOCH:
24 Q. Right. And can you tell me

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1 from which Mylan valsartan API lots all
2 the samples that might have been on hand
3 at Teva Jerusalem came from?
4 A. That is information I don't
5 have at my disposal at this moment.
6 MS. LOCKARD: And objection.
7 It's outside the 30(b)(6)
8 deposition notice.
9 MR. STANOCH: All right.
10 Why don't we take a break?
11 THE WITNESS: Okay.
12 VIDEO TECHNICIAN: The time
13 is now 2:53 p.m. We are going off
14 the record.
15 - - -
16 (Whereupon, a brief recess
17 was taken.)
18 - - -
19 VIDEO TECHNICIAN: The time
20 is now 3:11 p.m. Back on the
21 record.
22 MR. STANOCH: Mr. Barreto,
23 thank you for your time today and
24 yesterday. I appreciate it. I

<p style="text-align: right;">Page 685</p> <p>1 have no further questions at this 2 time. 3 I'll reserve my remaining 4 time for re-cross. I'll pass it 5 to Ms. Lockard. Thank you. 6 THE WITNESS: I appreciate 7 the opportunity to work with you. 8 MS. LOCKARD: Let me ask, I 9 assume nobody -- none of the other 10 parties have questions, at this 11 point, of Mr. Barreto? 12 Okay. How much time do -- 13 have we been on the record? 14 VIDEO TECHNICIAN: Today? 15 Four hours and 16 minutes. 16 MS. LOCKARD: Today, four 17 hours and 16 minutes? 18 VIDEO TECHNICIAN: Yes. 19 MS. LOCKARD: Okay. 20 All right. 21 - - - 22 EXAMINATION 23 - - - 24 BY MS. LOCKARD:</p>	<p style="text-align: right;">Page 687</p> <p>1 labeling that is being used in the United 2 States, FDA-approved labeling? 3 A. No. 4 Q. That's not being used 5 currently; is that correct? 6 A. Correct. 7 Q. And as a generic 8 manufacturer, do you have any 9 understanding regarding compliance 10 with -- of a generic, compliance with the 11 labeling of the reference branded drug? 12 A. There is compliance. 13 Q. But do you -- why is there 14 compliance, in terms of the generic 15 being -- and having to match the 16 referenced drug? 17 A. Can you clarify the 18 question, please? 19 Q. That was a bad question. 20 So is it -- does Teva, from 21 your perspective in quality, if you 22 understand this, Teva, does it generate 23 its own -- and did it generate its own 24 labeling language for the valsartan</p>
<p style="text-align: right;">Page 686</p> <p>1 Q. All right. Mr. Barreto, 2 just for the record, I'm Victoria 3 Lockard, your counsel and counsel for 4 Teva, as you're aware. And I'm going to 5 follow up on some questions here. 6 A. Okay. Thank you. 7 Q. So I'm going to jump around 8 and take you all the way back to some of 9 the discussions from yesterday as well. 10 A. Okay. 11 Q. Let me just ask you for 12 clarification. 13 Is it -- do you have an 14 understanding as to whether Teva has any 15 valsartan product currently on the market 16 in the United States? 17 A. There is no product. 18 MR. STANOCH: Objection to 19 form. 20 Go ahead. 21 BY MS. LOCKARD: 22 Q. So do you have any 23 understanding as to whether or not there 24 are any -- there is any valsartan</p>	<p style="text-align: right;">Page 688</p> <p>1 product when it was on the U.S. market? 2 A. That is correct. 3 Q. Does it -- did the Teva 4 generic brand labeling conform to the 5 branded -- reference listed branded 6 drug's labeling? 7 A. That is correct. 8 MR. STANOCH: Objection to 9 form. 10 BY MS. LOCKARD: 11 Q. And are you aware of any 12 requirement for a generic manufacturer 13 that their labeling must conform to the 14 branded referenced listed drug? 15 MR. STANOCH: Objection. 16 Sorry. Objection to form. 17 THE WITNESS: The 18 expectations are that the generic 19 drug product must comply with the 20 labeling requirements for -- to 21 generate product. 22 BY MS. LOCKARD: 23 Q. And in quality, and you're 24 in quality, did you have any involvement</p>

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1 in terms of input on what the language of
2 the labeling would be for a generic drug
3 like valsartan?
4 A. No.
5 Q. Whose responsibility was
6 that?
7 A. That would be -- that would
8 be mostly the regulatory organization.
9 Q. Earlier today -- and do you
10 have access to your exhibits?
11 A. Yes.
12 Q. If I can direct you, you
13 were asked about Exhibits-173 and 174,
14 which were e-mail discussions with
15 respect to sales of other sartans in
16 other countries.
17 A. Do you want me to open 173
18 first?
19 Q. Sure. Go ahead and pull up
20 173.
21 A. Okay. Yes.
22 Q. Did these e-mails, 173 or
23 174, did these e-mails suggest that Teva
24 was diverting product it could not sell

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1 in the U.S. to other countries?
2 A. No.
3 Q. Does this -- do the e-mails
4 indicate that Teva was selling valsartan
5 to other countries after it stopped
6 selling on the United States market?
7 A. The proposal of the e-mail
8 was to look for sartan solutions, not
9 necessarily valsartan, that could be used
10 to fulfill the expectations that we had
11 for risk/benefit access of patients to
12 medication.
13 Q. And -- okay. So when you
14 say "sartan solutions," what do you mean
15 by that?
16 A. There are different types of
17 drugs within the sartan category. You've
18 got losartan in this case; you've got
19 irbesartan; and there are other sartans
20 that could represent alternative
21 solutions to meet the needs of patient
22 access.
23 Q. And if you look at the
24 bottom of the e-mail, I believe 173, what

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1 started this discussion, it looks like
2 there was reference to an article.
3 Do you see that?
4 A. Yes, I do.
5 Q. Do you have an understanding
6 of what that article said or what it
7 conveyed?
8 A. That is -- that is correct.
9 It's -- the concern is about the extent
10 to which our actions, whatever they were
11 going to be, would impact on drug
12 shortage -- on the drug shortage
13 situation.
14 Q. And so there was a
15 discussion about the use of losartan?
16 A. That is correct.
17 Q. Was that one of the sartan
18 solutions that was being discussed?
19 A. That is correct.
20 Q. And ultimately, it looks
21 like, Mr. Vanderweeen asks for your
22 impression with regard to use of losartan
23 or other sartans in other markets aside
24 from the U.S.?

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1 A. Correct. So we were looking
2 for whatever best solution would fulfill
3 expectations of patient access.
4 Q. And do you see your response
5 on Exhibit Number 173?
6 A. You're speaking about March
7 27th at 2026 at the top?
8 Q. My computer just froze.
9 Yes. So I'm looking at the
10 March 27th, 2019, e-mail that is at 2026.
11 A. Correct.
12 Q. And if you follow along, it
13 says, I think the specific country
14 colleagues can work this out with their
15 respective authorities. Every authority
16 has its own perspective on how to deal
17 with patient access and patient safety.
18 Do you see that?
19 A. That is correct. I see it.
20 Q. What did you mean by those
21 statements?
22 A. The meaning of the statement
23 is that it was our responsibility to
24 ensure that we could provide to the

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1 authorities options that they would have
2 to consider in terms of ensuring that
3 they could have the ability to provide
4 their patient population, knowing that no
5 access was also a safety issue, an
6 important one.
7 In the end, the objective
8 was that it was the regulatory authority
9 of each country with which we discussed,
10 the one that would make the decision as
11 to whether or not a product could be
12 allowed for use in their respective
13 jurisdiction.
14 Q. So did Teva, then,
15 coordinate with the regulatory
16 authorities in each of these countries in
17 order to reach a conclusion about whether
18 or not other sartans could continue to be
19 marketed in countries like Chile?
20 A. That is correct, we did.
21 Q. And, to your knowledge, did
22 Teva ever distribute or sell any sartan
23 product that was in excess of any
24 requirements, limitation or regulations

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1 for nitrosamine levels in any country?
2 MR. STANOCH: Objection to
3 form.
4 THE WITNESS: No.
5 BY MS. LOCKARD:
6 Q. You briefly, way back,
7 yesterday, early in the day, you
8 mentioned that you had worked for the
9 FDA, correct?
10 A. That is correct.
11 Q. When did you work for the
12 FDA?
13 A. I started in 1977. I spent
14 19 and-a-half years with the agency. And
15 so I was a drug specialist or consumer
16 safety officer working with the
17 inspection of complex operations,
18 manufacturing operations in the
19 pharmaceutical industry.
20 Q. So what did your roles
21 entail during that almost 20 years you
22 worked for the FDA?
23 A. My roles included being an
24 analyst. I was a consumer safety officer

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1 or investigator. I was a supervisor of
2 investigators. I worked several -- under
3 several conditions in the headquarters
4 organization assisting with policies. I
5 worked with the ICH process on their
6 special projects. I did international
7 inspections. And I also did criminal
8 investigations for the agency.
9 Q. And in your experience with
10 the FDA, did you have occasion to receive
11 and review field alerts?
12 A. Yes, I did.
13 Q. And did you have an
14 occasion, with your experience at FDA, to
15 receive and review health hazard
16 assessments?
17 A. Yes, I did.
18 Q. And did you, in your
19 experience at FDA, have occasion to
20 review or to prepare 483s?
21 A. I did.
22 Q. And same with respect to
23 EIRs, in connection with your work at
24 FDA, were part of your involvement -- did

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1 that also involve preparing or reviewing
2 EIRs and responses thereto?
3 A. I did.
4 Q. Okay. So did you rely on
5 any of your FDA experience when you were
6 at Teva in order to fulfill your role as
7 the head of quality at Teva?
8 A. I had the FDA experience
9 looking at the regulations as a regulator
10 and then, obviously, from my years of
11 experience in the industry, applying the
12 regulations in a practical manner.
13 Q. And, to your knowledge, is
14 that, in fact, one of the reasons why you
15 were hired at Teva, because of this long
16 history with the FDA and ability to
17 understand those processes?
18 MR. STANOCH: Objection to
19 form.
20 THE WITNESS: As I
21 understand it, that was a critical
22 factor in my selection.
23 BY MS. LOCKARD:
24 Q. Your expertise does not

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1 include toxicology?
2 A. I'm not a toxicologist.
3 Q. Did Teva have a toxicologist
4 on board to review issues related to
5 genotoxic impurities?
6 A. That would be correct.
7 Q. Who was the toxicologist?
8 A. That would be Rafi Nudelman.
9 Q. And did you work with Rafi
10 Nudelman in connection with the
11 nitrosamines issue?
12 A. On many occasions, that's
13 what we did; we coordinated, yes.
14 Q. And you were asked some
15 questions about carcinogenicity or
16 potency of a mutagenic carcinogen and
17 questions of that nature.
18 Do you recall those from
19 yesterday?
20 A. I do.
21 Q. And are those areas within
22 your expertise?
23 A. They are not.
24 Q. Are these areas in which you

Page 698

1 would defer?
2 A. I would defer any
3 conclusions or assessments that would be
4 made in that area to Dr. Nudelman.
5 Q. You were asked about why the
6 word "potent" appears in some documents
7 but not in others, and specifically why
8 it doesn't appear in the recall notice.
9 Do you recall that?
10 A. I do.
11 Q. And was it your decision --
12 your decision not to include the word
13 "potent" in the recall?
14 A. In preparation of the recall
15 notice, we put the information that we
16 felt that was important to present to the
17 FDA. I had no specific considerations in
18 the selection of words, only to put the
19 facts together the best way I knew it.
20 Yes.
21 Q. Okay. So you were involved
22 in crafting of that recall notice, along
23 with others at Teva --
24 A. Correct.

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1 Q. -- is that right?
2 But was it -- was it a
3 specific decision of yours to omit the
4 word "potent"?
5 A. No.
6 Q. Do you recall any effort at
7 Teva to hide the word "potent" from the
8 recall notice?
9 A. No.
10 Q. Do you recall any
11 discussions specifically about whether or
12 not potent should be in or out of the
13 recall notice?
14 A. No.
15 Q. Was the word "potent," was
16 it necessary in order to convey the class
17 or the level of the recall?
18 MR. STANOCH: Objection to
19 form.
20 THE WITNESS: In my opinion,
21 and based on my experience, what
22 we wanted to put together was a
23 statement that would reflect the
24 facts of the case as we knew them

Page 700

1 at the time. And that's what we
2 did.
3 BY MS. LOCKARD:
4 Q. And was -- did FDA have any
5 input into the recall notice?
6 A. Yes. They actually perform
7 a review. And in that review they would
8 propose that we put certain words,
9 certain terms. And whatever
10 recommendations they make, we
11 incorporate.
12 Q. Did FDA make any
13 recommendations to include the word
14 "potent"?
15 A. No, they did not.
16 Q. If -- from your experience
17 at FDA, if FDA had wanted the word
18 "potent" to be included, what options
19 could they do --
20 A. They would have included
21 that as part of their recommendation.
22 Q. You were asked some
23 questions about a Mylan product hold for
24 the finished dose that was made with the

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1 Mylan API. I believe that was yesterday.
2 Do you recall?
3 A. I recall that question, yes.
4 Q. And what is your
5 understanding about whether or not the
6 Mylan API valsartan was put on hold at
7 any point in time?
8 A. So the reason for the
9 putting of -- hold of the Mylan product
10 at the time we knew about the ZHP
11 situation, was intended as a conservative
12 approach to immediately assess the extent
13 to which, you know, we needed to turn
14 that immediate recall into a more --
15 let's say into a longer hold. And that
16 was not the case.
17 Q. Okay. So what was Teva's
18 justification for releasing the Mylan API
19 product --
20 MR. STANOCH: Objection to
21 form.
22 THE WITNESS: Again, at the
23 time when we placed the product on
24 hold, we didn't have any reason to

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1 put it on hold other than the
2 issue that was associated with
3 ZHP. There was no direct link.
4 So when we removed it, we
5 did it based on the fact that at
6 the time, we did not have any
7 specific information that would
8 indicate that there was any
9 problem with the Mylan product.
10 BY MS. LOCKARD:
11 Q. Okay. And, you know, is
12 there -- would there be any benefit to
13 patients' interest in releasing that
14 product from hold?
15 MR. STANOCH: Objection
16 to --
17 THE WITNESS: Absolutely.
18 MR. STANOCH: Objection to
19 form.
20 BY MS. LOCKARD:
21 Q. What was the interest -- how
22 could that benefit patients, to release
23 product from the hold in this situation?
24 MR. STANOCH: Same

Page 703

1 objection.
2 THE WITNESS: So, the ZHP
3 hold, with the understanding that
4 this was going to cause a
5 significant drug shortage, was
6 sufficient reason for us, then, to
7 consider other options that we had
8 at hand.
9 And at the time, we had no
10 reasons to believe that the Mylan
11 product needed to be placed on
12 hold. So at that point, we felt
13 that it was important to continue
14 distributing product to ensure
15 patient access to medication.
16 VIDEO TECHNICIAN: The time
17 is 3:29 p.m. Going off the
18 record.
19 - - -
20 (Whereupon, a brief recess
21 was taken.)
22 - - -
23 VIDEO TECHNICIAN: The the
24 time is now 3:32 p.m. Back on the

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1 record.
2 BY MS. LOCKARD:
3 Q. So before the break, I was
4 asking you about the reasons why Teva
5 would not -- the reasons why Teva would
6 release the Mylan product from its hold.
7 And so you had mentioned
8 that the -- you were balancing the
9 shortage concern in an instance.
10 What do you mean by -- what
11 did you mean by that?
12 A. So in every consideration
13 when you put product on hold, one of the
14 expectations that regulators have is,
15 what is going to be the impact of that
16 action that you're going to take?
17 So we are well aware of the
18 regulatory expectations. So we're
19 looking for two things. One is the --
20 not creating a drug shortage situation
21 that would -- could put patients' access
22 to the medication at risk. And then, of
23 course, making sure that there is patient
24 access itself, because -- because of a

Page 705

1 potential safety issue for the patient if
2 the medication is not available.
3 So it was -- it was one of
4 those decisions where you have to look
5 for that balance, with the understanding
6 that, in the end, what you're seeking is
7 to ensure patients' access and safety.
8 Q. And at the time that that
9 hold was released, was there any testing
10 or evidence that Mylan's API was --
11 contained the nitrosamine impurity?
12 MR. STANOCH: Objection.
13 THE WITNESS: That is --
14 that was at a time when the only
15 knowledge that we had of any
16 contamination issue or impurity
17 present in API, such as valsartan,
18 was related only to the ZHP. We
19 had no reason to believe, at that
20 point, that not only Mylan, but
21 any other distributors of product,
22 would have the same situation.
23 So from our perspective, we
24 didn't have any reasons to put the

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1 product on hold.
2 BY MS. LOCKARD:
3 Q. Okay. And let me ask that
4 question just slightly different.
5 Did Teva have any
6 information, from Mylan or otherwise,
7 when Teva released the hold that
8 indicated the product -- the API
9 contained nitrosamines impurities?
10 MR. STANOCH: Objection to
11 form.
12 THE WITNESS: No.
13 MR. STANOCH: Mr. Barreto,
14 I'm just going to ask that you
15 wait ten seconds to let me object
16 if I need to. Thank you.
17 THE WITNESS: Thank you. My
18 apologies, counsel.
19 BY MS. LOCKARD:
20 Q. Okay. So you were asked
21 yesterday, I believe, about the reduced
22 testing program at the Jerusalem site.
23 Do you recall that?
24 A. Yes.

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1 Q. And is the -- was the
2 reduced testing program -- is that a
3 reduction in frequency or the kinds of
4 tests or something else?
5 A. The reduced testing program
6 involves the frequency with which you
7 implement the testing activities that are
8 required for an API in this case.
9 And that is justified by the
10 established history of reliability of
11 that API performance.
12 Q. Did the fact that that API
13 was on a reduced testing schedule -- in
14 your root cause analysis, did you
15 determine that the reduced testing
16 program in any way contributed to the
17 nitrosamine presence?
18 MR. STANOCH: Objection to
19 form.
20 THE WITNESS: No.
21 BY MS. LOCKARD:
22 Q. And did -- in your analysis
23 and investigation, did -- was there any
24 conclusion that that reduced testing

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1 program in any way delayed or prevented
2 the detection of the nitrosamine issue?
3 MR. STANOCH: Objection to
4 form.
5 THE WITNESS: No, because
6 the test method that was used for
7 both reduced testing and, let's
8 say, batch-after-batch testing was
9 the same one.
10 And that analytical test
11 method would not allow the company
12 to detect the impurities that
13 would have -- that would be
14 detected. You need a different
15 analytical test method to achieve
16 that.
17 BY MS. LOCKARD:
18 Q. So would the -- would the
19 outcome or the timeline for the discovery
20 of nitrosamines, would that have been any
21 different if that API supply had not been
22 on a reduced testing program?
23 MR. STANOCH: Objection to
24 form.

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1 THE WITNESS: The outcome
2 would not have changed in the end,
3 because whether you did reduced
4 testing or full testing, you would
5 not have been able to detect this
6 impurity.
7 BY MS. LOCKARD:
8 Q. So you were also shown some
9 EIRs regarding observations found at the
10 Teva facility where valsartan was
11 manufactured in Jerusalem.
12 Do you recall those
13 documents?
14 A. Yes, yes.
15 Q. And from your review of
16 those -- had you reviewed those prior to
17 your deposition?
18 A. Yes.
19 Q. And do any of those EIRs or
20 483s from Teva's Jerusalem facility, did
21 they involve nitrosamines?
22 A. No.
23 Q. Did any of those EIRs or
24 483s involve any impurity -- or the

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1 detection or failure to detect any
2 impurity in valsartan?
3 MR. STANOCH: Objection to
4 form.
5 THE WITNESS: No.
6 BY MS. LOCKARD:
7 Q. All right. There was -- let
8 me ask you this: In response to a 483,
9 is it typically Teva's practice to issue
10 a formal response back to the FDA?
11 A. It is a practice.
12 Q. And with respect to EIRs, is
13 Teva's practice to, likewise, respond to
14 those EIRs to the FDA?
15 A. The EIR is the outcome of a
16 process whereby, if a 483 was issued and
17 a response was submitted, the EIR comes
18 later on, after you have not only
19 received the 483 but also after you have
20 provided a response to -- to the FDA.
21 Q. And that was probably a poor
22 question on my part.
23 But the EIR from the FDA,
24 does that typically address whether or

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1 not the issues raised in the 483s have
2 been resolved?
3 A. Yes.
4 May I correct? Two things,
5 whether they were resolved because we
6 resolved them during inspection or we
7 submitted corrective actions -- evidence
8 of corrective actions of completion prior
9 to the issuance of the EIR, or whether we
10 made a commitment to corrective actions
11 that the agency understands those
12 corrective actions would be acceptable.
13 Q. And does Teva have policies
14 that require that process to be done,
15 meaning they have to implement corrective
16 actions in response to a 483?
17 A. Yes.
18 Q. And did you see -- in terms
19 of the issues that were discussed in the
20 483s or EIRs that you were shown for
21 Teva, do you have any reason to think
22 that Teva would not have corrected any
23 observations that were noted?
24 MR. STANOCH: Objection to

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1 form.
2 THE WITNESS: No.
3 BY MS. LOCKARD:
4 Q. You were also shown the 2016
5 internal audit of the Jerusalem facility
6 by Teva.
7 Do you recall that?
8 A. I do.
9 Q. And if you need to look at
10 those documents, I have the exhibit list.
11 I can direct you if you need to.
12 But so did Teva have a
13 program for internal auditing of its own
14 facilities?
15 A. Teva has a program for
16 what's called self-inspection, which
17 means that the facilities do their own
18 internal audit. And then there's a
19 corporate audit program where corporate
20 auditors go to each facility to perform
21 the audit, a GMP audit.
22 Q. Okay. So in this instance,
23 for the 2016 audit of the Jerusalem
24 facility, was that a corporate audit that

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1 was performed?
2 A. That was a corporate audit,
3 yes.
4 Q. And what are the purposes of
5 such corporate audits?
6 A. Every corporate audit is
7 part of the process whereby companies
8 pursue what I called self-regulation.
9 So what that means is that
10 the audit is intended for the companies
11 to find their own deficiencies, to then
12 identify corrective actions for those
13 deficiencies, and to improve the state of
14 compliance of the facilities to that
15 corrective action program.
16 Q. And in this instance, do you
17 believe that Teva initiated the
18 corrective actions in response to the
19 findings in the 2016 audit?
20 A. Yes.
21 MR. STANOCH: Objection to
22 form.
23 THE WITNESS: Sorry,
24 counsel.

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1 BY MS. LOCKARD:
2 Q. Is there any reason to think
3 that any of those issues that were
4 discovered remained unaddressed or
5 uncorrected?
6 A. No.
7 Q. Have you seen or learned
8 anything that would indicate to you that
9 the issues addressed in the 2016
10 corporate audit had any impact on Teva's
11 ability to detect nitrosamines in
12 valsartan API?
13 MR. STANOCH: Objection to
14 form.
15 THE WITNESS: No.
16 And, again, the reason for
17 that is that the analytical test
18 methods that were used to evaluate
19 the quality profile of the APIs
20 were test methods that would not
21 allow you to detect those
22 impurities.
23 BY MS. LOCKARD:
24 Q. Okay. And so were there any

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1 applicable pharmaceutical regulations,
2 standards or limits related to
3 nitrosamines prior to 2018?
4 A. No. Nor were there any
5 guidance from any regulatory authorities.
6 Q. And you were asked about
7 capabilities that Teva may have had to
8 perform testing to identify nitrosamines.
9 Do you recall that line of
10 questioning?
11 A. I do.
12 Q. And did Teva have a
13 methodology, prior to 2018, for
14 identifying nitrosamines?
15 A. No.
16 Q. And in order to develop the
17 testing, what does Teva, or others in the
18 industry, need to do before they can
19 implement such testing?
20 A. As I indicated yesterday,
21 you need to identify the right piece of
22 equipment that you would use for the
23 testing. And then you would need to
24 develop an analytical test method that

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1 would allow you to have that method
2 implemented.
3 But in the end, that
4 analytical test method has to be a
5 validated test method. So it has to
6 fulfill specific expectations for what a
7 validated test method is.
8 Q. What do you mean by
9 validation of the test method?
10 A. So there are a number of
11 factors that are considered, like
12 reproducibility, repeatability -- I'm
13 trying to remember now the other terms
14 that were used -- robustness, that sort
15 of a factor, that you have to demonstrate
16 that the method can fulfill those
17 expectations.
18 Q. So did -- so now there is
19 one or more methodologies for detection
20 of NDMA, correct?
21 A. Can you repeat the question?
22 My apologies.
23 Q. Sure.
24 There -- currently there are

Page 717

1 one or more methodologies for detection
2 of NDMA --
3 A. That is correct.
4 Q. And the methodology for NDEA
5 has also been developed?
6 A. That is correct.
7 Q. Okay. And are those the
8 same methodologies, to your knowledge?
9 A. To my knowledge, that may
10 not be the case. Each -- and this is
11 where a little bit of the complexity
12 comes up.
13 If you have a test method
14 for NDMA for tablets, finished drug
15 product, that test method may or may not
16 be applicable to an API. You may -- you
17 may have the need to adjust that method
18 to make it applicable to the API or vice
19 versa.
20 The same for NDEA. Your
21 NDMA method may not be automatically
22 suitable for you to test for NDEA. So
23 you have to demonstrate -- and you could
24 probably do it, but you still have to

Page 718

1 demonstrate that that's the case.
2 Q. Okay. So are you saying
3 that if you have a methodology for NDMA,
4 that does not necessarily mean that
5 methodology would work for NDEA?
6 A. That is correct.
7 Q. And does the methodology
8 differ depending on the process or --
9 either the process or the root cause for
10 the presence of the nitrosamines?
11 A. That is correct.
12 Q. You were also asked about
13 Teva's various facilities having the
14 presence of a gas chromatography machine.
15 Do you remember that?
16 A. I do.
17 Q. And are there different
18 kinds of gas chromatography machines?
19 A. That is correct. And, you
20 know, you've got GC-MS, and then you've
21 got GC with -- for which you may
22 different detectors, like, yesterday
23 counsel talked about NP detector.
24 So not all sites would have

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1 the same capabilities. And that was part
2 of the discussion we were having.
3 Q. So as you sit here today, do
4 you know whether the GC machines that
5 Teva had, prior to 2018, had the
6 detection capabilities to detect
7 nitrosamine, either NDMA or NDEA?
8 MR. STANOCH: Objection to
9 form.
10 THE WITNESS: Mr. Binsol
11 will speak a little bit more about
12 that, on the details.
13 But that was part of the
14 strategic approach that we were
15 taking, trying to identify whether
16 the different facilities had all
17 the capabilities that were
18 necessary for us to implement the
19 test -- the analytical test
20 methods.
21 BY MS. LOCKARD:
22 Q. You had one comment
23 yesterday, just briefly, about FDA
24 advising that patients continue to take

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1 their medications.
2 Do you recall that?
3 A. I do.
4 Q. Why was that noteworthy to
5 you?
6 A. It was important because
7 it's part of that process, where even
8 when the -- we -- FDA was telling us to
9 advise -- giving us advice on the recall
10 activity, the advice was that patients
11 needed to still have a discussion with
12 their healthcare professionals and
13 pharmacists to ensure that the safety of
14 the patient, from access to the
15 medication, could be ascertained.
16 So my take on this is that
17 FDA understood that this was a very
18 important and critical point where
19 patient safety and the risk/benefit ratio
20 had to be taken into consideration.
21 Q. To your knowledge, did any
22 of the recalled valsartan that was for
23 sale in the United States fail to meet
24 applicable specifications at the time?

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1 MR. STANOCH: Objection to
2 form. Vague.
3 THE WITNESS: Yes.
4 BY MS. LOCKARD:
5 Q. So while we understand the
6 criticism here is that Teva and others
7 did not identify nitrosamines,
8 notwithstanding that, did the recall of
9 valsartan meet its applicable
10 specifications?
11 MR. STANOCH: Objection to
12 form.
13 THE WITNESS: Can you
14 clarify the question, please?
15 BY MS. LOCKARD:
16 Q. I can.
17 Despite the -- despite the
18 absence of any knowledge regarding the
19 presence of nitrosamines in the valsartan
20 used for the U.S. market, did the Teva
21 valsartan meet its applicable
22 specification at all times?
23 A. Understood.
24 MR. STANOCH: Objection to

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1 form. It was asked and answered.
2 THE WITNESS: Yes. They met
3 the established specification,
4 correct.
5 BY MS. LOCKARD:
6 Q. Okay. Why, in your view,
7 was the industry caught by surprise by
8 this nitrosamine issue?
9 MR. STANOCH: Objection to
10 form. Leading.
11 MS. LOCKARD: What is
12 leading about that?
13 MR. STANOCH: It lacks
14 foundation, counsel. He never
15 testified to any surprise. This
16 wasn't even part of the scope of
17 the topics.
18 MS. LOCKARD: His topic
19 includes --
20 MR. STANOCH: You can't put
21 "why" in front of the question --
22 a leading question and convert it
23 to a direct question, counsel. I
24 object.

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1 BY MS. LOCKARD:
2 Q. Was the industry caught by
3 surprise by nitrosamines, Mr. Barreto?
4 MR. STANOCH: Objection to
5 form. Lacks foundation.
6 THE WITNESS: I think that
7 there was -- it was very clear in
8 the message that the regulators
9 generated that this impurity was
10 unexpected. And if something is
11 unexpected and all of the sudden
12 is present, then of course, this
13 is a surprise.
14 And what makes it a surprise
15 is that, first, when you look at
16 the ZHP, I mean, you are --
17 situation -- you're talking about,
18 you know, traces of diethylamine
19 coming in contact with nitrous
20 acid. This is something that was
21 not predicted. So if it was not
22 predicted, of course you're going
23 to be surprised.
24 BY MS. LOCKARD:

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1 Q. So why was the industry
2 caught by surprise by the nitrosamine
3 issue?
4 A. From my perspective, there
5 was no FDA guidance around this. So the
6 regulators, you know, and not only in the
7 U.S. but in Europe and other countries,
8 no -- there's no indication anywhere in
9 any guidance, in any regulation,
10 including the Pharmacopeia, that we
11 needed to test for something that was not
12 expected to be there.
13 So I think that it was not
14 just the industry, but regulators did not
15 know about this either.
16 Q. Okay. You were asked a lot
17 of questions about the timing of the
18 field alert that was submitted initially
19 on July 3rd, 2018.
20 Do you recall that?
21 A. Yes.
22 Q. And what is the purpose of
23 the field alert?
24 A. As I indicated yesterday,

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1 the purpose of a field alert is to
2 provide a signal to the regulatory agency
3 that the filer of the field alert report
4 has an indication that a product that is
5 in distribution within the United States
6 may be the subject of a quality or safety
7 issue.
8 Q. So the -- not just any
9 quality issue rises to the level of a
10 field alert, correct?
11 A. That is correct.
12 Q. And so what is the criteria
13 for a reportable event, as it would apply
14 in this case?
15 A. So it -- it should be one
16 that gives the regulators the -- the
17 perspective that, in our opinion, based
18 on the initial findings that we have
19 made, that there may be a potential
20 action against product on the market.
21 And it is in our best
22 interest to let the regulators know so
23 that they are advised.
24 Q. Under the regulations, does

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1 it need to be a significant quality
2 issue?
3 MR. STANOCH: Objection.
4 THE WITNESS: It is -- it is
5 my opinion that not all issues
6 rise to that level. So
7 significant, meaning, again, that
8 there is a potential impact on
9 quality and safety, and that
10 that's a suspicion.
11 BY MS. LOCKARD:
12 Q. And in order for it to rise
13 to a reportable event, does it have to be
14 one that impacts product in distribution?
15 A. That is correct.
16 Q. Who at Teva makes the
17 decision as to whether information
18 received from a supplier would meet the
19 criteria for a reportable event?
20 A. That would be the quality
21 organization at the different sites, and
22 then that discussion is escalated at the
23 corporate level. And then that
24 submission is made to the FDA.

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1 Q. Okay. So is the decision
2 one of quality or regulatory, or is it
3 both?
4 A. It is a quality decision.
5 It is a quality decision.
6 You may have input from
7 other organizations, like regulatory.
8 But at the end, it's a quality decision.
9 Q. Okay. When did Teva --
10 Teva's quality department make the
11 determination that a reportable event had
12 occurred?
13 A. That was on June 28th, 2018.
14 Q. How many business days later
15 did Teva report that to the FDA?
16 A. So that was on a Thursday.
17 So -- and, again, there's always
18 discussions around this, counsel.
19 But Thursday would be the
20 first day, Friday would be the second
21 day, Monday would be the third day. But,
22 again, there's discussions. Because --
23 so they say, well, you received it on the
24 28th, the 29th is the first day, then et

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1 cetera.
2 But the important thing is
3 that, you know, from an FDA perspective,
4 from my experience, the most important
5 thing for the FDA is not whether or not
6 you submitted it within three days or
7 four days or five days, it's the extent
8 to which you are able to demonstrate that
9 you are submitting a report that is
10 worthy of their review and their
11 reaction, if necessary.
12 Q. To your knowledge, did the
13 FDA ever complain to Teva about the
14 timing of the report?
15 A. Not in this case, and
16 very -- I would say, no, not in this
17 case.
18 Q. If FDA have a problem with
19 the timing of the report, what --
20 ultimately, what can they do?
21 A. You know, during the course
22 of inspections, one of the activities
23 that the FDA looks at is the performance
24 of the field alert -- field alert

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1 program.
2 So, for instance, yeah, a
3 timely submission may be one of the --
4 those criteria. And they could cite you
5 for that type of observation, whether
6 it's an isolated situation or a systemic.
7 Obviously, a systemic situation is
8 something that they would be very
9 concerned with, not necessarily with an
10 isolated situation.
11 But then they also are
12 interested -- they are also interested in
13 whether or not the proper investigation
14 was submitted and whether or not we --
15 you know, we update the FDA with routine
16 updates on the progress and closure of
17 the investigation.
18 Q. Did FDA ever cite Teva for
19 any system failures, or otherwise, with
20 respect to their compliance of the field
21 alert program?
22 A. No.
23 Q. Did FDA ever take any issue
24 or issue any adverse findings with

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1 respect to how Teva handled the
2 investigation into the root cause of the
3 nitrosamine?
4 A. No.
5 Q. To your knowledge, did FDA
6 ever complain to Teva about any aspect of
7 Teva's root cause evaluation of the
8 nitrosamine issues?
9 A. No.
10 Q. You were asked if you
11 oversaw SOPs, and I think you said yes.
12 But can -- are you able to
13 clarify, is that you oversaw the SOPs for
14 quality --
15 A. Yes.
16 Q. -- is that right?
17 A. That is correct.
18 Q. Okay. And you did not --
19 did you have any involvement in SOPs for
20 the legal department?
21 A. No.
22 Q. Did you oversee or have
23 involvement in SOPs for the regulatory
24 department?

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1 A. No.
2 Q. You were asked about one
3 policy, which was Exhibit-135, if you
4 want to pull that up.
5 It was the outsourced
6 activities contract manufacture and
7 analysis document.
8 A. I do remember that -- that
9 policy.
10 Q. In connection with the
11 supply of valsartan API to Teva, was ZHP
12 considered a contract manufacturer?
13 A. No.
14 Q. Does the Exhibit-135,
15 involving contract manufacture, apply to
16 the valsartan API relationship between
17 Teva and ZHP?
18 MR. STANOCH: Objection to
19 form.
20 THE WITNESS: It would apply
21 as an API supplier.
22 BY MS. LOCKARD:
23 Q. Okay. The document itself
24 applies to -- and if you need to pull it

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1 up -- it applies to contract
2 manufacturers, correct?
3 A. Yes.
4 Q. And ZHP, I think you said,
5 was not a contract manufacturer; it was
6 an API supplier?
7 A. It is an API supplier, not a
8 contract manufacturer, within the
9 definition of what the contract
10 manufacturer is.
11 Q. Okay. So would Exhibit-135
12 have -- regarding contract manufacturer
13 have applied to the valsartan API
14 relationship between Teva and ZHP?
15 MR. STANOCH: Objection.
16 THE WITNESS: No.
17 BY MS. LOCKARD:
18 Q. And the same question for
19 Mylan, was Mylan considered a contract
20 manufacturer?
21 A. No.
22 Q. So would Exhibit-135,
23 governing contract manufacturers, have
24 applied to the Mylan/Teva relationship?

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1 A. No.
2 Q. You were asked about change
3 control processes yesterday.
4 Do you recall that?
5 A. Yes.
6 Q. And does Teva have a process
7 for evaluating change -- process changes
8 of its suppliers?
9 A. Yes.
10 Q. And have you reviewed any
11 documents with respect to the change
12 control process Teva went through for the
13 ZHP process change in 2012?
14 A. Yes.
15 Q. Okay.
16 MS. LOCKARD: So, Steve
17 Harkins, do you have Bates number
18 0950662 available to pull up as an
19 exhibit?
20 MR. HARKINS: It should be
21 in the chat, everybody.
22 MS. LOCKARD: So you're not
23 able to drop it into the exhibits
24 that --

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1 MR. HARKINS: No. We
2 discussed on the break, I'm not
3 able to put it in there. But if
4 you open the chat, you can open a
5 native copy of it on your laptop.
6 MS. LOCKARD: I cannot.
7 It's not letting me open it.
8 MR. STANOCH: I've done it,
9 Mr. Harkins. Thank you.
10 MS. WHITELEY: I was able to
11 open it, but I had to try twice.
12 BY MS. LOCKARD:
13 Q. Can you identify this
14 document for us, Mr. Barreto?
15 A. I'm not able to see it.
16 Q. Oh, you're not able to open
17 it?
18 A. Do I need to go in the chat?
19 Q. Yes. See if you can open
20 it.
21 A. What document would that be?
22 Number 180?
23 Q. Do you have your chat
24 function open, because he wasn't able

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1 to --
2 A. My apologies, counsel.
3 Q. He wasn't able to -- it
4 looks like you got it.
5 - - -
6 (Whereupon, Exhibit
7 Teva-181,
8 TEVA-MDL2875-00060028-0034,
9 10/30/18 E-mail, Sawyer to
10 Barreto, as marked for
11 identification.)
12 - - -
13 THE WITNESS: Yes.
14 BY MS. LOCKARD:
15 Q. Okay. And you are -- you
16 are aware that ZHP notified Teva
17 regarding the 2012/2013 time period
18 process change, correct?
19 A. Right. My apologies. This
20 document is not that, the one I'm looking
21 at. My apologies.
22 Q. Hold on. Let's see if I can
23 pull it up.
24 A. Oh, okay. Let me see if

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1 this is it, counsel.
2 I have it, counsel. I have
3 it now.
4 Q. Let me see what you're
5 looking at.
6 A. Sorry. My apologies.
7 Q. Okay. Just for the record,
8 and to ensure that you have it, so on the
9 first page of that document you see the
10 Bates number at the bottom, 0950662?
11 A. Yes.
12 Q. What is this that we are
13 looking at?
14 A. This is -- this is the
15 change control document that is started
16 to proceed with all the activities that
17 would be necessary to implement a change.
18 Q. Okay. And so does this --
19 when you say "procedures," do you mean
20 this was -- is this a record of what Teva
21 was doing to evaluate the change?
22 A. It's a record that initiates
23 the process and gets the process going,
24 in terms of all the things that have to

<p>Page 737</p> <p>1 be done to ensure that you can support 2 that a change control was implemented 3 correctly. 4 Q. Okay. And you had 5 mentioned, when you were reviewing the 6 CBE 30, that there was some evaluation 7 with regard to the different steps that 8 were identified and that it was 9 identified as a minor to moderate change? 10 A. Correct. 11 Q. And is this document -- does 12 this show the process by which the 13 evaluation was initiated to try to reach 14 those conclusions? 15 A. That is correct. 16 Q. Okay. Is the change control 17 process that's reflected in this 18 document, is that something that the 19 quality team would do, typically? 20 A. That is correct. And, of 21 course, with input into the change 22 control activities by the different 23 members of the organization. 24 Q. So did Teva take reasonable</p> <p>Page 738</p> <p>1 measures to evaluate the change that was 2 submitted by ZHP consistent with its 3 change control process? 4 MR. STANOCH: Objection to 5 form. 6 THE WITNESS: It is my 7 opinion, based on the review that 8 I've done of the change, that a 9 significant number of activities 10 were conducted, in that the 11 process is documented. 12 There was a -- for instance, 13 an impact assessment, QA review; 14 and every stage, when every 15 activity was done, there was 16 documentation as to who was 17 supposed to do what, all the way 18 until the change completion 19 allowed the regulatory group to 20 eventually file the ANDA 21 supplement. 22 BY MS. LOCKARD: 23 Q. So you were asked about the 24 CBE 30s and the ANDA supplement. And I</p>	<p>Page 739</p> <p>1 believe those were Exhibits-2 and 3 -- 2 A. Yes. 3 Q. -- if you want to pull those 4 up. 5 And, you know, you 6 established that -- or testified that 7 Teva did not do its own independent 8 testing of the DMF and MTBE solvents. 9 A. DMF and MTBE solvents, 10 correct. 11 Q. Did I misstate that? Okay. 12 So let me ask you, why did 13 Teva not do testing on the solvents? 14 A. As I indicated to Counsel 15 Stanoch, FDA had -- I'm sorry, Teva had 16 performed this change control process and 17 performed a number of assessments and 18 risk assessments and investigations, 19 testing activities that let Teva conclude 20 that the new product was fulfilling the 21 expectations set by the regulators. 22 Q. Are you aware of any 23 regulations or FDA guidances that would 24 prohibit Teva from relying on the</p> <p>Page 740</p> <p>1 supplier's testing of the supplier's 2 solvents? 3 A. No. 4 Q. And is there -- is there 5 anything inconsistent with what Teva did, 6 in relying on the supplier and the 7 supplier's testing, anything inconsistent 8 with industry standards or practices 9 based on your experience? 10 MR. STANOCH: Objection to 11 form. 12 THE WITNESS: I do not see 13 any inconsistency. 14 Once again, the purpose of 15 the challenges that Teva was doing 16 was to confirm that the quality 17 attributes of the -- let's call it 18 the revised version of the API, 19 fulfilled the original 20 expectations set for the original 21 version of the API. 22 BY MS. LOCKARD: 23 Q. And was it necessary or 24 required by any guidance, rule,</p>
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1 regulation or industry standard that Teva
2 disclose to the FDA that the testing was
3 done by the supplier and not the
4 finished-dose maker?
5 MR. STANOCH: Objection to
6 form.
7 THE WITNESS: No, no.
8 BY MS. LOCKARD:
9 Q. And was there any effort at
10 Teva to try to hide the fact of who did
11 the testing --
12 MR. STANOCH: Objection to
13 form.
14 BY MS. LOCKARD:
15 Q. -- when it reported to the
16 FDA?
17 MR. STANOCH: Objecting to
18 form.
19 THE WITNESS: No.
20 BY MS. LOCKARD:
21 Q. Was, to your knowledge,
22 anybody at Teva -- or have you seen any
23 evidence that anybody at Teva was trying
24 to mislead the FDA into thinking they did

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1 their own testing?
2 MR. STANOCH: Objection to
3 form.
4 THE WITNESS: No.
5 BY MS. LOCKARD:
6 Q. Is there any reason to think
7 that if Teva had done its own testing,
8 that those -- that testing would have
9 shown anything different than what ZHP's
10 testing showed?
11 MR. STANOCH: Objection to
12 form.
13 THE WITNESS: No. And if
14 the testing had shown anything
15 different, then there would have
16 been a discussion between Teva and
17 the supplier.
18 BY MS. LOCKARD:
19 Q. But based on your
20 understanding today, is there any reason
21 to think that if Teva had done the same
22 test, Teva would have come up with a
23 different result than ZHP?
24 A. No.

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1 MR. STANOCH: Objection.
2 BY MS. LOCKARD:
3 Q. You were shown a document,
4 Exhibit-165.
5 And you mentioned, when you
6 were reviewing that document, that there
7 was watermark across it that said,
8 Canceled document.
9 Do you remember that?
10 A. I do.
11 Q. What does a canceled
12 document watermark mean to you?
13 A. It means that that document
14 is no longer an official document.
15 Therefore, it's one that no longer
16 represents, you know, the official
17 statements that would be made with
18 respect to the purpose of that document.
19 Q. Okay. You were also asked
20 about the audit report from May 2018, the
21 audit of ZHP.
22 A. Yes.
23 Q. And I believe that -- I
24 don't have the exhibit in front of me,

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1 but if you need to look at it, it's
2 Exhibit-61, I believe.
3 A. Allow me to go there for a
4 second, please.
5 Yes.
6 Q. And you were asked, you
7 know, is there a reference to -- a
8 specific reference to the auditor
9 reviewing the 483 with the supplier.
10 Do you recall that?
11 A. That is correct. Yes, I do.
12 Q. And you said there is no
13 specific reference to that. There was a
14 discussion on the record where, you know,
15 I took issue with the questioning, and
16 opposing counsel took issue with my
17 response.
18 But I had said, if you're
19 searching for 483, you're not going to
20 find it, correct?
21 A. That is correct.
22 Q. Is there a reference in here
23 anywhere to the inspection -- the FDA
24 inspection that was done that resulted in

<p>Page 745</p> <p>1 the 483?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And is there any</p> <p>4 reference in the document to the EIR,</p> <p>5 which would have followed the 483?</p> <p>6 A. That is correct.</p> <p>7 If you go to the end of the</p> <p>8 document, on Page 62 of 62 -- my</p> <p>9 apologies. Let me find it.</p> <p>10 That would be Page 59 of 62.</p> <p>11 The auditor, as part of the attachments</p> <p>12 that he or she collected, makes reference</p> <p>13 in their Attachment 1 to the U.S. Food</p> <p>14 and Drug Administration EIR cover letter,</p> <p>15 Chuannan site, 2017/05.</p> <p>16 Q. And this is listed in the</p> <p>17 attachment that has, essentially, an</p> <p>18 index of material?</p> <p>19 A. That is correct.</p> <p>20 Q. And from your experience,</p> <p>21 what does that signify about the items</p> <p>22 that were listed on that index?</p> <p>23 A. Correct. What that -- what</p> <p>24 that tells to me is that the auditor</p> <p>Page 746</p> <p>1 asked to have evidence that the FDA had</p> <p>2 conducted that inspection, and the</p> <p>3 evidence would have been in the form of</p> <p>4 the EIR that would have been released.</p> <p>5 The auditor was given a copy</p> <p>6 of the cover letter. In this instance,</p> <p>7 the cover letter would have indicated</p> <p>8 that the 2017 inspection was considered</p> <p>9 an acceptable inspection, in spite of the</p> <p>10 observations that were issued.</p> <p>11 Q. So from the reference --</p> <p>12 MR. STANOCH: I'm sorry,</p> <p>13 excuse me. I can't -- I've lost</p> <p>14 my volume. I can't hear any of</p> <p>15 you. Can we go off the record for</p> <p>16 two seconds?</p> <p>17 MS. LOCKARD: Sure.</p> <p>18 VIDEO TECHNICIAN: The time</p> <p>19 is 4:16 p.m. Going off the</p> <p>20 record.</p> <p>21 - - -</p> <p>22 (Whereupon, a brief recess</p> <p>23 was taken.)</p> <p>24 - - -</p>	<p>Page 747</p> <p>1 VIDEO TECHNICIAN: The time</p> <p>2 is now 4:16 p.m. Going back on</p> <p>3 the record.</p> <p>4 BY MS. LOCKARD:</p> <p>5 Q. So from review of what you</p> <p>6 just described, what conclusion can you</p> <p>7 draw about whether the auditor was aware</p> <p>8 of the 483 and discussed the issues in</p> <p>9 the 483?</p> <p>10 A. That the --</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: From my</p> <p>14 perspective, the auditor asked for</p> <p>15 any -- for the first and foremost</p> <p>16 important evidence that the</p> <p>17 previous inspection was</p> <p>18 successful, which is the copy of</p> <p>19 the EIR. What the company did is</p> <p>20 that they gave the auditor Page 1,</p> <p>21 which is the cover letter.</p> <p>22 And that cover letter would</p> <p>23 indicate that the inspection was</p> <p>24 found acceptable and that the</p> <p>Page 748</p> <p>1 corrective actions that were</p> <p>2 implemented were adequate, as far</p> <p>3 as the FDA is concerned.</p> <p>4 BY MS. LOCKARD:</p> <p>5 Q. Okay. You can put that</p> <p>6 exhibit away.</p> <p>7 As part of the quality team,</p> <p>8 was it expected that you, Mr. Barreto,</p> <p>9 would review and weigh in on the HHA that</p> <p>10 Dr. Liu was overseeing?</p> <p>11 A. It is customary, and, again,</p> <p>12 based on my experience, that, you know,</p> <p>13 the HHA will be prepared by the medical</p> <p>14 organization and that different</p> <p>15 individuals that have an interest in</p> <p>16 the -- in the description of the HHA</p> <p>17 would look at it, review it, and provide</p> <p>18 recommendations, which is what I did.</p> <p>19 Q. So is it unusual for someone</p> <p>20 in the quality department to make</p> <p>21 suggestions to the HHA?</p> <p>22 A. No.</p> <p>23 MR. STANOCH: Objection to</p> <p>24 form.</p>
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1 BY MS. LOCKARD:
2 Q. Are there others from other
3 departments that might weigh in on the
4 HHA, regulatory or others?
5 A. Yes. There's nothing in the
6 regulation or in practice that would
7 prevent that review to take place.
8 Q. And so, you know, we went
9 through some suggestions that you had
10 made for the document.
11 Were your revisions to the
12 language incorporated?
13 A. Yes.
14 Q. Did Dr. Liu, who was
15 responsible for finalizing the report, to
16 your knowledge, did he agree with your
17 suggestions?
18 A. The only way that he would
19 put that into the HHA would be if he
20 agreed.
21 Q. And so did he sign off on
22 the final HHA, which incorporated your
23 suggestions?
24 A. Yes, he did.

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1 Q. And did Dr. Liu, or anyone,
2 ever indicate to you that they were
3 uncomfortable with the language you had
4 proposed?
5 A. No.
6 Q. Is that -- the language that
7 you had proposed, is that the kind of
8 language that you had been familiar with
9 and seen in your experience at the FDA,
10 for 20 years, looking at HHAs?
11 MR. STANOCH: Objection to
12 form.
13 THE WITNESS: Again, it's
14 based on the input that we had
15 from different regulatory
16 authorities, in terms of what the
17 issue represented.
18 So what we wanted to convey
19 in that recommendation we were
20 making was the facts as we know
21 them at the time.
22 BY MS. LOCKARD:
23 Q. But when you approached an
24 HHA in this instance, or another, do you

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1 harken back to your days at the FDA in
2 terms of the filter that you use to
3 evaluate and make recommendations or
4 improvements to that HHA?
5 MR. STANOCH: Objection to
6 form.
7 THE WITNESS: Yes, I do.
8 BY MS. LOCKARD:
9 Q. You were asked a few times
10 about the absence of a quality agreement
11 with Mylan.
12 Do you recall that?
13 A. I do.
14 Q. Does Teva have a quality
15 agreement with every supplier of
16 ingredients in its products?
17 A. I would say that more than
18 likely that's not the case, because there
19 are different reasons why that is not
20 going to happen.
21 Q. And what are some of the
22 reasons that that might not be able to be
23 achieved?
24 A. So --

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1 MR. STANOCH: Objection.
2 THE WITNESS: -- as I had
3 indicated -- sorry, counsel.
4 MR. STANOCH: It's okay.
5 THE WITNESS: It's a -- it's
6 a mutual agreement and
7 understanding. So we set the
8 expectation for ourselves, meaning
9 Teva, but we still have to
10 persuade and convince the other
11 organization that we would like
12 for them to enter into that
13 agreement.
14 BY MS. LOCKARD:
15 Q. And does the absence of a
16 quality agreement with the supplier in
17 any way limit your ability to perform
18 those quality functions that you would
19 expect to be described in a quality
20 agreement?
21 MR. STANOCH: Objection to
22 form.
23 THE WITNESS: No.
24 BY MS. LOCKARD:

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1 Q. And if you'll pull up the
2 quality agreements, that were produced
3 and used in your deposition, with ZHP --
4 I think if you pull up 167, Exhibit-167,
5 that was the first.
6 A. Yes, counsel.
7 Q. And had you reviewed these
8 quality agreements, 167 through 170, in
9 preparation for your deposition?
10 A. I have browsed through them,
11 yes.
12 Q. Are these -- the ZHP quality
13 agreement, did they appear to be typical
14 of the type of quality agreements that
15 Teva would have if -- when -- if and when
16 it did enter into quality agreements?
17 MR. STANOCH: Objection to
18 form.
19 THE WITNESS: That is
20 correct.
21 BY MS. LOCKARD:
22 Q. If Teva had a Mylan quality
23 agreement, is it fair to assume that it
24 would have looked something like these?

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1 MR. STANOCH: Objection to
2 form. Lacks foundation. Calls
3 for speculation.
4 Go ahead.
5 BY MS. LOCKARD:
6 Q. Well, Mr. Barreto, you've
7 seen quality agreements with suppliers
8 before, correct?
9 A. I have to tell you that the
10 language and the expectations set by
11 almost any quality agreement that is
12 within this industry will address the
13 issues that are described here.
14 Q. Yeah. And so what are some
15 of the issues that are described?
16 You know, what -- let me
17 ask, what is the -- what are the
18 provisions, generally speaking, of a
19 quality agreement?
20 A. So they set the conditions
21 under which certain communications will
22 take place. So that indicated -- and
23 then how the relationship between the two
24 organizations will -- so, for instance,

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1 for audit, the quality agreements say
2 that ZHP will allow -- shall allow
3 Actavis to conduct a facility site
4 compliance audit.
5 This is what the quality
6 agreement says. But I think, to go to
7 the relationship with Mylan, we do
8 perform routine quality audits of the
9 Mylan facility, for instance.
10 With respect to
11 investigations, you know, Section 10.1
12 says that ZHP shall be responsible for
13 and use commercially reasonable efforts
14 to investigate a test that fails to meet
15 the specifications. This is the same
16 expectation that is set for Mylan, not
17 only by the quality agreement but also by
18 the regulations.
19 So what the quality
20 agreement does is that it just sets a
21 number of understandings between --
22 between the two organizations.
23 Q. And that's my point. I'm
24 not trying to represent that a Mylan

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1 quality agreement would look exactly like
2 this one.
3 But we're accused of not
4 having a quality agreement with Mylan.
5 So I would like to get your guidance on
6 what we would have expected to see in a
7 quality agreement with Mylan.
8 MR. STANOCH: Objection.
9 What's the question? Are you
10 asking him what we would have seen
11 in a nonexistent agreement?
12 Objection. Vague.
13 BY MS. LOCKARD:
14 Q. What provisions would you
15 expect to see in a typical quality
16 agreement with a supplier like Mylan?
17 A. With respect to Mylan, I
18 would say that a quality agreement, more
19 or less similar to what we have for ZHP,
20 would be -- would be that type of
21 agreement.
22 Q. And so would the -- for
23 example, the responsibilities that are
24 listed out in the ZHP agreement, would

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1 those generally be the same types of
2 responsibilities that would be listed in
3 a Mylan agreement?
4 A. That is correct.
5 MR. STANOCH: Objection to
6 form. Calls for speculation.
7 Lacks foundation. Vague and
8 ambiguous.
9 Go ahead.
10 BY MS. LOCKARD:
11 Q. Well, are you familiar with
12 supply -- quality supply agreements --
13 quality agreements with suppliers, Mr.
14 Barreto?
15 A. Can you repeat the question?
16 Q. Are you familiar with
17 quality agreements with suppliers?
18 A. Yes.
19 Q. So this is -- this is not a
20 foreign document to you, correct?
21 MR. STANOCH: Objection to
22 form.
23 THE WITNESS: Yes.
24 BY MS. LOCKARD:

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1 Q. Did you -- did you ever have
2 occasion to review quality supply --
3 excuse me, quality agreements with
4 suppliers when you were at FDA?
5 A. Yes.
6 Q. And so are they fairly
7 standard in terms of the types of general
8 provisions they govern?
9 MR. STANOCH: Objection to
10 form.
11 THE WITNESS: As I indicated
12 to you, counsel, when I look at
13 this supplier quality agreement,
14 it is a typical example of what a
15 quality agreement would look like,
16 in this case, for an API
17 organization.
18 If I looked at the quality
19 agreement for a finished drug
20 product, there would be certain
21 things that would be somewhat
22 different. But the expectations
23 in general would be relatively
24 similar.

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1 BY MS. LOCKARD:
2 Q. And despite not having this
3 piece of paper setting out these types of
4 responsibilities and expectations, did
5 Teva endeavor to follow the same
6 responsibilities, expectations, you know,
7 audit roles that are described in a
8 typical quality agreement like you see
9 with ZHP or like you've seen in other
10 instances in your experience?
11 MR. STANOCH: Objection to
12 form.
13 THE WITNESS: The type of
14 information that we needed to
15 obtain from Mylan to come to a
16 conclusion on, for instance,
17 during audits, on the state of
18 their facilities, if during audits
19 we issued observations, they would
20 implement corrective actions the
21 same way that they would be
22 implemented under the expectations
23 of the quality agreement.
24 The -- if -- if an

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1 investigation is generated, they
2 communicated that information to
3 us the same way it would have been
4 communicated through a quality
5 agreement.
6 Any follow-up interactions
7 between Mylan and us were followed
8 the same way they would have
9 achieved through a quality
10 agreement.
11 So the absence -- in my
12 opinion, based on my
13 responsibility, the absence of a
14 quality agreement does not
15 necessarily imply that a company
16 is not able to manage, supervise,
17 monitor, interact with a supplier
18 of service or a product.
19 BY MS. LOCKARD:
20 Q. So would you expect there to
21 be anything new or different in the piece
22 of paper that is the quality agreement
23 that Teva and Mylan were not already
24 doing in practice?

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<p>1 MR. STANOCH: Objection to 2 form. Calls for speculation. 3 Vague and ambiguous. Lacks 4 foundation. 5 Go ahead, sir. 6 THE WITNESS: My expectation 7 is that the absence of -- my 8 perspective on this is that the 9 absence of a quality agreement 10 does not prevent the company from 11 achieving its objectives of 12 managing, supervising, monitoring 13 and interacting with a supplier in 14 any way, shape or form. 15 BY MS. LOCKARD: 16 Q. If there had been a quality 17 agreement in place with Mylan, do you 18 have any opinion as to how the outcome or 19 the timeline would have been different 20 than it was in the absence of such a 21 written piece of paper? 22 MR. STANOCH: Objection to 23 form. 24 THE WITNESS: It is my</p>	<p>1 course of these events if Teva had had a 2 quality agreement with Mylan? 3 MR. STANOCH: Objection to 4 form. 5 THE WITNESS: From my 6 perspective, I don't see any 7 significant difference. As I have 8 indicated, a quality agreement is 9 a good tool to have. 10 But in this case, the 11 absence of it does not necessarily 12 represent that that would make a 13 significant difference in 14 achieving the objectives that we 15 would have to manage, supervise, 16 monitor and track with a supplier 17 of an API. 18 I'd like to ask for a 19 five-minute recess, if that's 20 okay. 21 MS. LOCKARD: Sure. That's 22 fine. And I'm getting close to 23 the end, so I'll just review my 24 notes and see. I'll probably have</p>
Page 762	Page 764
<p>1 opinion that under the 2 circumstances that we were 3 operating, the outcome of the 4 investigation and the closure of 5 the issues at Mylan were not any 6 different than what we achieved 7 through our interactions with ZHP. 8 BY MS. LOCKARD: 9 Q. Well, did any failure to 10 have a quality agreement with Mylan lead 11 to the failure to detect the nitrosamines 12 in the Mylan API? 13 MR. STANOCH: Objection to 14 form. 15 THE WITNESS: No. No. 16 BY MS. LOCKARD: 17 Q. And did your root cause 18 analysis at Teva, in evaluating the 19 nitrosamine issue in the Mylan API, did 20 it list as a root cause failure to have a 21 quality agreement with Mylan? 22 A. No. 23 Q. So in your view, what 24 difference would it have made in the</p>	<p>1 a few more questions for you. 2 Let's just do that. 3 Is that all right with 4 everybody? 5 MR. STANOCH: Yes. 6 THE WITNESS: Counsel, would 7 you agree to that? I appreciate 8 that. 9 MR. STANOCH: Of course. 10 THE WITNESS: Thank you. 11 VIDEO TECHNICIAN: The time 12 is 4:32 p.m. Going off the 13 record. 14 - - - 15 (Whereupon, a brief recess 16 was taken.) 17 - - - 18 VIDEO TECHNICIAN: The time 19 is now 4:39 p.m. Back on the 20 record. 21 BY MS. LOCKARD: 22 Q. Mr. Barreto, if you can turn 23 to Exhibit-172. 24 This was an e-mail from Eric</p>

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1 Drape regarding the comment about, we did
2 better than Mylan.
3 A. Yes.
4 Q. Do you have that pulled up?
5 A. Yes.
6 Q. When he was saying "we did
7 better than Mylan," what is your
8 understanding or impression of who he was
9 talking about?
10 A. I think, based on the
11 individuals that were cited in the
12 e-mail, meaning John Mason, Noa Anker,
13 myself, the communication is about the
14 fact that, you know, in terms of
15 addressing the different issues
16 associated with the nitrosamines, that
17 we, the TAPI organization, had done a
18 better -- a great job at managing, you
19 know, these issues.
20 Q. And so you were -- in your
21 role, did you provide quality guidance
22 for both Teva and the subsidiary API
23 supplier TAPI?
24 A. That is correct.

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1 Q. So who -- the other two
2 individuals on that e-mail, are they with
3 TAPI?
4 A. Correct.
5 Q. So, then, to answer the
6 question as to who "we" is, is it your
7 impression that "we" is Teva or TAPI?
8 MR. STANOCH: Objection to
9 form.
10 THE WITNESS: From my
11 perspective, it -- it was around
12 TAPI.
13 BY MS. LOCKARD:
14 Q. And -- well, strike that.
15 So, you know, you've been
16 here for two full days now, Mr. Barreto,
17 and you've been examined with a lot of
18 documents and questions.
19 Have you heard or seen
20 anything in the last two days to shake
21 your confidence that Teva acted promptly
22 and appropriately in response to trying
23 to investigate and address the
24 nitrosamine issue?

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1 MR. STANOCH: Objection to
2 form.
3 THE WITNESS: No.
4 BY MS. LOCKARD:
5 Q. And is that your feeling
6 with respect to how Teva responded, that
7 they responded promptly and responsibly?
8 MR. STANOCH: Objection to
9 form.
10 THE WITNESS: Yes.
11 BY MS. LOCKARD:
12 Q. Overall, were you
13 comfortable, as the head of quality, with
14 how Teva responded?
15 MR. STANOCH: Objection to
16 form.
17 THE WITNESS: Yes.
18 BY MS. LOCKARD:
19 Q. Okay. Can you explain that?
20 A. When you look at the -- this
21 issue, how it first came up and how it
22 evolved in a way that it had such a
23 significant impact on -- from a global
24 perspective, on patients' access to

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1 medication and the way in which we
2 interacted with our API suppliers, the
3 way we interacted with the regulators,
4 the way we interacted, you know,
5 internally within Teva and the way in
6 which we assembled an important
7 organization that handles a product that
8 extended above and beyond, close to a
9 year or more, I mean, this was -- this
10 was an incredible process.
11 Where -- the thing that
12 characterized the process is, we moved in
13 a very expedient way, in terms of the
14 actions that we took. As the issues
15 evolved, we were able to manage and to
16 maintain the organization's focus on what
17 was most important, which is, one,
18 removing product that needed to be
19 removed, and then looking for ways to
20 provide an access to patients, a product
21 that we could provide, and then in the
22 end, looking for and working with our
23 suppliers on the solution, which is to
24 ensure that our suppliers would be in a

<p>Page 769</p> <p>1 good position to have the right 2 manufacturing process in place that would 3 allow us, then, to eventually resume 4 operations, both delivering product that 5 would meet the -- now, this new set of 6 specifications and expectations for the 7 entire world.</p> <p>8 MS. LOCKARD: I think those 9 are all the questions I have for 10 you, unless there are additional 11 issues that are raised by opposing 12 counsel's questions.</p> <p>13 So just bear with us for a 14 few moments, and we'll see if we 15 can wrap this up.</p> <p>16 MR. STANOCH: Mr. Barreto, 17 I'm going to have to ask you a few 18 more questions. Thanks again for 19 your patience today.</p> <p>20 - - - 21 EXAMINATION 22 - - -</p> <p>23 BY MR. STANOCH: 24 Q. You don't -- do not think</p>	<p>Page 771</p> <p>1 I -- as I indicated to you, 2 I would not accept an operation of a 3 contract manufacturing activity where 4 there was an absence of a quality 5 agreement, because that -- in that case, 6 the quality agreement enforces 7 expectations that the supplier of the 8 contract services must fulfill as if I 9 was fulfilling those.</p> <p>10 Q. Quality agreements are 11 important enough that the FDA thinks it 12 should review them, correct?</p> <p>13 A. Excuse me?</p> <p>14 Q. Quality agreements are 15 important enough that the FDA believes 16 they should review them, correct?</p> <p>17 A. When those quality 18 agreements are present and they ask for 19 them and they are present, then they look 20 for a way to ensure that the expectations 21 set by the two organizations are 22 maintained.</p> <p>23 Q. You said when you were at 24 the FDA you reviewed quality agreements,</p>
<p>Page 770</p> <p>1 that a quality agreement is simply a 2 piece of paper, do you?</p> <p>3 A. What I do believe is that a 4 quality agreement is one way of achieving 5 the objectives that -- the quality 6 agreement is one of a number of elements 7 that we use to provide an infrastructure 8 for, as I said, the management and 9 supervision and oversight.</p> <p>10 What I'm trying to say, 11 counsel, is that it is a good idea to 12 have a quality agreement. I'm not saying 13 that. But the opposite is not -- does 14 not mean that the absence of a quality 15 agreement prevents an organization from 16 achieving its objectives.</p> <p>17 There are hundreds of 18 organizations today where there is no 19 quality agreement in place, and we still, 20 across the globe, ensure that we, you 21 know, manage our quality and compliance 22 activities in spite of the absence of 23 quality agreements under certain 24 instances.</p>	<p>Page 772</p> <p>1 right?</p> <p>2 A. I did. I did.</p> <p>3 Q. Right. And you're aware, 4 I'm sure, that the FDA has guidance for 5 the industry on quality agreements; 6 you're aware of that, right?</p> <p>7 A. Of course.</p> <p>8 Q. Right. And that guidance, 9 which came out years after your departure 10 from the FDA, you're aware that it talks 11 about the importance of quality 12 agreements, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. And that having a quality 15 agreement is an important piece in 16 ensuring GMP compliance, correct?</p> <p>17 A. That is correct.</p> <p>18 But I'm also aware that the 19 absence of a quality agreement does not 20 automatically imply that the company will 21 receive a 483 for not having one.</p> <p>22 Q. And you also agree, as we 23 saw yesterday, that the quality 24 agreements are important enough that Teva</p>

<p style="text-align: right;">Page 773</p> <p>1 has an entire SOP about it, correct?</p> <p>2 A. Yes. And I indicated to you</p> <p>3 that, when I looked at that policy, the</p> <p>4 focus on contract manufacturing is really</p> <p>5 the most important part.</p> <p>6 Because for the other</p> <p>7 activities, if a supplier refuses to do a</p> <p>8 quality agreement with me, that does not</p> <p>9 necessarily mean that I'm not going to</p> <p>10 use that supplier, because that's not in</p> <p>11 the regulations.</p> <p>12 Q. Is API the most important</p> <p>13 aspect of a finished-dose product?</p> <p>14 A. It's --</p> <p>15 MS. LOCKARD: Objection.</p> <p>16 Vague.</p> <p>17 THE WITNESS: It's one of</p> <p>18 the important elements of the</p> <p>19 final finished drug product. It's</p> <p>20 important from the standpoint that</p> <p>21 it provides a therapeutic value.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Absolutely. In fact,</p> <p>24 because of that, it's the most important</p>	<p style="text-align: right;">Page 775</p> <p>1 supposed to have, correct?</p> <p>2 A. Yes. And my perspective on</p> <p>3 this is that the absence of the quality</p> <p>4 agreement does not prevent a</p> <p>5 manufacturing company from achieving the</p> <p>6 objectives of ensuring that an API</p> <p>7 supplied is going to fulfill the</p> <p>8 expectations of the specifications set or</p> <p>9 the manufacturing conditions under which</p> <p>10 that API is manufactured.</p> <p>11 Q. You would agree, though,</p> <p>12 it's certainly much easier to achieve</p> <p>13 those objectives with a quality</p> <p>14 agreement, correct?</p> <p>15 MS. LOCKARD: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I've seen it</p> <p>18 in different ways, counsel.</p> <p>19 So in some cases, you have</p> <p>20 the quality agreement and</p> <p>21 organizations are not able to --</p> <p>22 and I'm not talking about Teva,</p> <p>23 I'm talking about from my</p> <p>24 experience.</p>
<p style="text-align: right;">Page 774</p> <p>1 ingredient in a finished-product drug,</p> <p>2 wouldn't you say?</p> <p>3 MS. LOCKARD: Objection.</p> <p>4 Vague.</p> <p>5 THE WITNESS: The way in</p> <p>6 which that API now is processed is</p> <p>7 what makes it important.</p> <p>8 It's -- so what I'm trying</p> <p>9 to say is that there are different</p> <p>10 activities within the management</p> <p>11 and processing of that API that</p> <p>12 make it important.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. So what's more important to</p> <p>15 you, the processing of the API or the API</p> <p>16 itself?</p> <p>17 A. They are both equally</p> <p>18 important to me.</p> <p>19 Q. Right. And you want to make</p> <p>20 sure that anyone who is doing that</p> <p>21 manufacturing of that API do it in a</p> <p>22 consistent, cGMP-compliant methodology to</p> <p>23 ensure that the product is of the quality</p> <p>24 and purity and strength that it's</p>	<p style="text-align: right;">Page 776</p> <p>1 The enforcement of the -- of</p> <p>2 the quality agreement is,</p> <p>3 basically, nil. So I think that,</p> <p>4 again, even the generation of a</p> <p>5 quality agreement is one element</p> <p>6 of the process.</p> <p>7 There are other activities</p> <p>8 that take place that actually are</p> <p>9 able to, with or without a quality</p> <p>10 agreement, ensure that a company</p> <p>11 is compliant with regulations.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Your counsel asked you some</p> <p>14 questions about the -- a method that had</p> <p>15 to be developed to test for nitrosamines.</p> <p>16 Do you recall that</p> <p>17 generally?</p> <p>18 A. Could you repeat the</p> <p>19 question?</p> <p>20 Q. Your counsel asked you some</p> <p>21 questions about methods used to test API.</p> <p>22 A. Yes.</p> <p>23 Q. And I might have misspoke, I</p> <p>24 think maybe the context -- and you can</p>

<p>Page 777</p> <p>1 correct me if I'm wrong -- but it might 2 have been about the methods that would be 3 used to measure the specifications of 4 API? 5 A. And, counsel, I'm sorry, so 6 what is the question? 7 Q. I'm just asking you, I think 8 you -- you tell me. 9 Did you testify that it's 10 important to have a validated method 11 before -- 12 A. Yes. 13 Q. Yes, right? Okay. Thank 14 you for helping. 15 MS. LOCKARD: Hold on. Let 16 him finish the question. 17 THE WITNESS: I apologize. 18 BY MR. STANOCH: 19 Q. Sure. Right. 20 Mr. Barreto, you recall 21 testifying on the importance of having a 22 validated method, correct? 23 A. Yes. 24 Q. And refresh us, what was the</p> <p>Page 778</p> <p>1 context of that? 2 A. The context of that is that 3 in order for us to identify -- for us to 4 test a product under the regulated 5 conditions, you must have a validated, 6 analytical test method in place to do 7 that to comply with regulations. 8 Q. And I think you were 9 inferring that Teva couldn't do testing 10 sooner than it did, of Mylan or ZHP 11 valsartan API, because it had to validate 12 a method first; is that right? 13 A. What I'm saying is that in 14 order -- one of the standards -- and I 15 had a lot to do with that, from my 16 perspective, and given the nature of this 17 new issue, one of the expectations that I 18 had, and we all embraced, was that in 19 order for us to be in a position to 20 deliver information, data, that was 21 reliable to FDA, and other regulatory 22 organizations, I wanted to ensure that 23 the analytical test method was validated. 24 You are working with very</p>	<p>Page 779</p> <p>1 small levels of these impurities. You 2 really need to make sure that you're able 3 to have a method that is very precise in 4 order to deliver the right, reliable 5 data. 6 Q. You didn't share the same 7 view at the time when all of these recall 8 issues hit in the second half of 2018, 9 correct? 10 MS. LOCKARD: Objection. 11 Vague. 12 THE WITNESS: The -- what we 13 did is that with the information 14 we had, with information that we 15 received, regardless of that -- 16 the status of the method that was 17 used, we proceeded to engage in 18 the recall. 19 So for us, the important 20 thing was the action that we took. 21 And we were not questioning -- if 22 they said that it was 59 PPMs, we 23 were not in the basis of saying, 24 oh, maybe your analytical test</p> <p>Page 780</p> <p>1 method is wrong, it should have 2 been less. 3 So we took that and we said 4 filate it. And we decided to 5 proceed with the recall action. 6 That's what we did. 7 MR. STANOCH: I'm going to 8 mark Teva -- 9 THE WITNESS: That's 10 still -- 11 MR. STANOCH: I'm sorry, 12 sir, are you done? 13 THE WITNESS: I'm sorry. 14 That still does not change my 15 expectation that the analytical 16 test method that I'm going to use 17 to provide data to the regulators 18 to defend -- especially to defend 19 product that is in distribution, 20 has to be validated. 21 MR. STANOCH: I'm marking 22 the next exhibit, Bates ending 23 60028. 24 - - -</p>
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1 (Whereupon, Exhibit
2 Teva-182, TEVA-MDL2875-00060028-0034,
3 10/30/18 E-mail, Sawyer to
4 Barreto, was marked for
5 identification.)
6 - - -
7 BY MR. STANOCH:
8 Q. Do you see that?
9 A. Just give me one second,
10 counsel.
11 Q. Tell me when you're ready.
12 A. What is the number?
13 MR. STANOCH: Is that 181?
14 MS. LOCKARD: I think it
15 should be 182.
16 BY MR. STANOCH:
17 Q. It's an e-mail chain.
18 Do you see that, sir?
19 A. Yes, sir.
20 Q. The topmost message is from
21 Corey Sawyer to you dated October 30th,
22 2018, subject, U.S. samples for testing.
23 Do you see that?
24 A. Yes, sir.

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1 Q. And do you recall this
2 e-mail chain?
3 A. Yes, sir.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 Q. Right. So --
19 A. And I can explain. I can
20 explain what --
21 Q. Well, let me ask my
22 questions -- then you can explain --
23 first, sir, thank you. That's how this
24 works.

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1 A. Thank you.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 784

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 MS. LOCKARD: Objection.
9 Form. Misstates the testimony.
10 THE WITNESS: Could I --
11 MS. LOCKARD: You can
12 explain.
13 THE WITNESS: I'd like to
14 explain, counsel.
15 MS. LOCKARD: Answer the
16 question, and then you can.
17 THE WITNESS: In this
18 specific case, the samples that we
19 were going to test were on product
20 that was already recalled.
21 So for -- from a regulatory
22 perspective, we were not
23 generating a validated test method
24 to release product, which is one

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1 of the core concepts of what we
2 do.
3 In this case, the FDA is
4 asking us to quickly do a certain
5 amount of work to deliver that
6 information to them.
7 In my opinion, the risk of
8 running those samples with a
9 nonvalidated test method did not
10 equate to the risk of running a
11 nonvalidated test method to
12 release product.
13 So in this case, I did not
14 see the need for us to run a
15 validated test method, in light of
16 the urgency that was set by the
17 agency for us to submit certain
18 data on product that was already
19 recalled and retrieved, counsel.
20 BY MR. STANOCH:
21 Q. And you're not aware of Teva
22 ever telling the FDA that it ran its test
23 samples -- or strike that.
24 You're not aware of whether

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1 Teva told the FDA that it generated test
2 results on a method that had not yet been
3 validated, correct?
4 A. I would have to look at the
5 next string of e-mails. If you have
6 them, I'll be more than glad to discuss
7 it with you.
8 Q. Do you recall whether
9 validation was done concurrently with the
10 testing?
11 A. I'm sorry, can you repeat
12 the question?
13 Q. Do you recall whether the
14 validation was done concurrently with the
15 actual testing?
16 A. I don't recall. I would say
17 that probably not.
18 Q. You can put that aside.
19 Sir, you mentioned, with
20 your counsel's questions, that the Teva
21 audit of ZHP from May 2018, that they --
22 that they saw the U.S. FDA EIR cover
23 letter concerning the -- that ZHP site,
24 right?

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1 A. That is correct.
2 Q. Right. There's no
3 indication here that the Teva auditors
4 saw the actual Form 483s, the
5 observations in the Form 483s, or
6 anything behind the cover letter; is that
7 correct?
8 A. The report does not speak
9 about that.
10 Q. It doesn't, right.
11 And, in fact, the cover
12 letter is simply going to be the
13 formality letter, right, you know this
14 from your years at the FDA, where they
15 simply say, we've completed our
16 investigation, right?
17 A. It will also say that we
18 have found that your corrective actions
19 are acceptable, and now you're classified
20 as an accepted, acceptable company.
21 Q. Right. And because Teva
22 apparently only had the cover letter,
23 they don't -- didn't actually get copies
24 of what the FDA 483 observations were,

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1 what the corrective actions were from
2 ZHP, and any response by the FDA to them;
3 is that right?
4 MS. LOCKARD: Objection.
5 Calls for speculation.
6 THE WITNESS: The report
7 does not speak about that one way
8 or the other.
9 BY MR. STANOCH:
10 Q. Do you have any reason to
11 believe, sitting here today, that Teva's
12 auditors, when they went to ZHP in May of
13 2018, had access to and reviewed the
14 FDA's Form 483 observations from its 2017
15 inspection?
16 A. I don't know what the
17 auditor did. So I am not willing to
18 speculate.
19 But I do know that the
20 auditor was persuaded that if the
21 corrective actions were acceptable to the
22 FDA, based on the classification given to
23 the inspection, then the auditor
24 proceeded to pursue a comprehensive audit

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1 of those areas that the auditor had, you
2 know, planned to cover.
3 Q. Right. But we don't know
4 that those areas were the same as those
5 focused on by the FDA from its 483,
6 right?
7 A. No.
8 Q. Right. And earlier with
9 your counsel you, I think, testified that
10 nitrosamines were a surprise; is that
11 right?
12 A. That is correct.
13 Q. You've been in the industry
14 for quite some time.
15 Nitrosamines are not a new
16 compound; is that right?
17 A. That is correct.
18 Q. Right. The knowledge -- the
19 industry knowledge about nitrosamines,
20 that goes back decades; is that fair to
21 say?
22 MS. LOCKARD: Objection.
23 Form.
24 THE WITNESS: From what I've

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1 read, the nitrosamines are known
2 to be in water, in foods, in
3 meats. The discussion -- and I
4 have not found -- as far as the
5 overall investigation process that
6 we performed, I did not find
7 anything anywhere that would
8 indicate to us that, in the pharma
9 industry, we had seen this type of
10 issue in any product that I'm
11 aware of.
12 BY MR. STANOCH:
13 Q. Is that right?
14 Did you -- what did you do,
15 as part of that investigation, to see
16 whether Teva had analyzed potential
17 nitrosamine contamination in any other
18 product?
19 A. No, what I'm saying is --
20 what I said is that I looked at
21 literature, I looked for guidance
22 documents in the different regulatory
23 websites of the different regulatory
24 bodies, I mean, including Canada.

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1 And we didn't see anything
2 that would indicate a problem -- I mean,
3 the entire organization was aware of the
4 issues that we had with valsartan. There
5 was no input from anybody, from anywhere,
6 that would indicate that, you know,
7 anybody was aware of this issue.
8 And there was widespread
9 communication about this.
10 Q. And I think you said
11 something to the effect of, there's no
12 way to detect nitrosamines at a low
13 enough level at the time, a method had to
14 be developed.
15 Is that what your testimony
16 was?
17 A. That is correct.
18 Q. Okay.
19 MR. STANOCH: I'm going
20 to -- I'm going to mark the next
21 exhibit, sir.
22 THE WITNESS: Yes, sir.
23 MR. STANOCH: Which number
24 should this be, Ms. Miller?

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1 MS. LOCKARD: 183.
2 COURT REPORTER: Correct,
3 183.
4 MR. STANOCH: Thank you,
5 all.
6 - - -
7 (Whereupon, Exhibit
8 Teva-183,
9 TEVA-MDL2875-00917708-7715, Test
10 Result Report, was marked for
11 identification.)
12 - - -
13 THE WITNESS: It's still
14 uploading, a couple of seconds.
15 Yes.
16 BY MR. STANOCH:
17 Q. Do you have that document in
18 front of you, sir?
19 A. Yes, sir.
20 Q. This appears to be a test
21 result report, dated July 2, 2014, from
22 Toxikon.
23 Do you see that?
24 A. Yes, sir.

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1 Q. Do you recall any
2 conversations about that, to begin with?
3 A. No, no.
4 Q. Do you recall ever hearing
5 about an article authored by Müller?
6 A. Yes.
7 Q. Do you recall an article
8 that's entitled, A Rationale for
9 Determining Testing and Controlling
10 Specific Impurities in Pharmaceuticals
11 That Possess Potential for Genotoxicity?
12 A. I do recall that.
13 Would you like to share that
14 document with me, please?
15 Q. Sure. My only question is,
16 do you recall looking at that document in
17 the summer of 2018?
18 A. I recall looking at that
19 document at some point in time, yes.
20 Q. Well, the specific question,
21 though, is, when did you look at it
22 first, sir?
23 A. I don't remember right now.
24 But I also looked at it recently.

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1 Q. Right. You looked at it to
2 prepare for today's deposition, because I
3 used it with Mr. Carlson's deposition,
4 right?
5 A. That is correct.
6 MS. LOCKARD: Object to
7 form. That's not why he looked at
8 it.
9 BY MR. STANOCH:
10 Q. Did you look -- you don't
11 recall, one way or the other, if you ever
12 saw this document while you were actually
13 employed at Teva between 2017 and 2019;
14 is that fair?
15 A. I don't recall if I saw it
16 at that time. But I am well aware of
17 that document.
18 Q. Okay. And your counsel made
19 a number of references about your FDA
20 experience. And I agree that you
21 certainly did work at the FDA after you
22 got your Bachelor of Science.
23 But you left the FDA when,
24 1996?

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1 A. I left the FDA in '96. I
2 was there since 1977.
3 Q. So you left the FDA before
4 the FDA Modernization Act of 1997,
5 correct?
6 A. That is correct.
7 Q. You left the FDA before the
8 Food and Drug Administration Amendments
9 Act of 2007, correct?
10 A. Yes.
11 Q. You left the FDA before the
12 Food and Drug Administration Safety and
13 Innovation Act of 2012, correct?
14 A. Yes.
15 Q. And, quite obviously, any
16 other FDA statutory enactments or
17 regulations, you had left the FDA by
18 '96 -- strike that.
19 You left the FDA prior to
20 any other statutory enactments from the
21 FDA from 1997 forward?
22 A. Except that in the different
23 positions that I have had, I have had to
24 become, myself, aware, knowledgeable and

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1 comfortable with all of those regulations
2 and laws that you're discussing.
3 Q. Sure. Right. In terms of
4 working in the private sector, your
5 consulting work, right?
6 A. Correct.
7 Q. Right. But you were not
8 asked, after 1996, to enforce any of
9 those laws anymore, right?
10 A. That is correct.
11 Q. Because you were no longer
12 at the FDA?
13 A. That is correct.
14 Q. You had no obligations to
15 enforce the 1997, 2007 or 2012 laws that
16 I referenced, because you had left the
17 FDA by the time they were instituted,
18 right?
19 MS. LOCKARD: Objection.
20 Asked and answered.
21 THE WITNESS: Not within the
22 FDA. But, obviously, all of those
23 regulations have to be now
24 implemented at the different

<p>Page 801</p> <p>1 facilities where I had 2 responsibility. 3 So I would not enforce it 4 externally -- as a member of the 5 FDA, but I would enforce it as a 6 member of the quality and 7 compliance organization in the 8 different companies that I worked 9 for. 10 MR. STANOCH: Give me a 11 moment, please. 12 THE WITNESS: Yes. 13 MR. STANOCH: You know what, 14 no further questions. Reserve 15 time if necessary. 16 MS. LOCKARD: No questions 17 from my end. The deposition is 18 concluded. Thank you. 19 THE WITNESS: Thank you, 20 everybody. I appreciate it. 21 MR. STANOCH: Mr. Barreto, 22 thank you so much for your 23 patience over these last two days 24 and appearing remotely. I</p> <p>Page 802</p> <p>1 appreciate it. 2 THE WITNESS: My pleasure. 3 MS. LOCKARD: He will read 4 and sign. So I think we've agreed 5 that at least Teva witnesses can 6 perform the errata by -- you know, 7 remotely -- 8 MR. STANOCH: No objection. 9 MS. LOCKARD: -- by 10 notarization. Okay. I'm losing 11 my train of memory here. But, 12 yeah, okay. 13 VIDEO TECHNICIAN: The time 14 is now 5:12 p.m. Going off the 15 record. 16 - - - 17 (Whereupon, the deposition 18 concluded at 5:12 p.m.) 19 - - - 20 21 22 23 24</p>	<p>Page 803</p> <p>1 CERTIFICATE 2 3 I, Amanda Maslynsky-Miller, Certified 4 Realtime Reporter, do hereby certify that 5 prior to the commencement of the examination, 6 DANIEL BARRETO, was remotely sworn by me to 7 testify to the truth, the whole truth and 8 nothing but the truth. 9 I DO FURTHER CERTIFY that the foregoing is a 10 verbatim transcript of the testimony as taken 11 stenographically by me at the time, place and 12 on the date hereinbefore set forth, to the 13 best of my ability. 14 I DO FURTHER CERTIFY that I am neither a 15 relative nor employee nor attorney nor 16 counsel of any of the parties to this action, 17 and that I am neither a relative nor employee 18 of such attorney or counsel, and that I am 19 not financially interested in the action. 20 21 22 23 24 Amanda Miller Certified Realtime Reporter Dated: April 19, 2021 (The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p> <p>Page 804</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the 12 errata sheet, which will be attached to 13 your deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days 17 of receipt of the deposition transcript 18 by you. If you fail to do so, the 19 deposition transcript may be deemed to be 20 accurate and may be used in court. 21 22 23 24</p>
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1 ACKNOWLEDGMENT OF DEPONENT
 2
 3 I, _____, do
 4 hereby certify that I have read the
 5 foregoing pages, 1 - 383, and that the
 6 same is a correct transcription of the
 7 answers given by me to the questions
 8 therein propounded, except for the
 9 corrections or changes in form or
 10 substance, if any, noted in the attached
 11 Errata Sheet.
 12
 13 DANIEL BARRETO DATE _____
 14
 15 Subscribed and sworn
 16 to before me this
 17 _____ day of _____, 20____.
 18
 19 My commission expires: _____
 20
 21 Notary Public _____
 22
 23
 24

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